Exhibit 01

AMERICAN ARBITRATION ASSOCIATION

In the Matter of the Arbitration between:

Summers Laboratories, Inc.,
Claimant / Counter-Respondent

v. **Case No. AAA 01-17-0004-4710**

Shionogi Inc.,
Respondent / Counter-Claimant

INTERIM AWARD

We, THE UNDERSIGNED ARBITRATORS, having been duly designated in accordance with the arbitration agreement contained in the Asset Purchase Agreement dated July 16, 2007 as amended entered into between Claimant Summers Laboratories, Inc., ("Claimant" or "Summers") and Sciele Pharma Cayman Ltd. which was acquired by Respondent Shionogi Inc. ("Respondent" or "Shionogi") and having been duly sworn, and having duly heard the proofs, allegations, and arguments by said Parties, do hereby issue this INTERIM AWARD.

I. THE PARTIES

Summers is a privately owned pharmaceutical and dermatological product company located in Collegeville, Pennsylvania. Summers was represented throughout the arbitration by the law firm of DLA Piper LLP, 1650 Market St., Suite 4900, Philadelphia, PA 19103.

Shionogi is the successor in interest to Sciele Pharma Cayman Ltd., which was acquired by Shionogi & Co., Ltd. Sciele was a pharmaceutical company specializing in sales, marketing and development of branded prescription products focused on the therapeutic areas of

cardiovascular, diabetes, women's health and pediatrics.[1] Shionogi was represented throughout the arbitration by Norton Rose Fulbright US LLP, 300 Convent St., Suite 2100, San Antonio, TX 78205.

II. OVERVIEW OF THE DISPUTE

The dispute between the parties concerns an Asset Purchase Agreement dated July 16, 2007 between Summers and Sciele, as amended by the March 17, 2017 First Amendment to the Asset Purchase Agreement (collectively, "the APA"). Under the APA, Shionogi developed Ulesfia, a product for killing head lice (the "Product"). The APA provided for an upfront payment by Shionogi at closing of $2 million and certain deferred payments. At issue are earn-out payments to be made through January 2022 with a minimum payment due if specified net sales levels were not achieved "other than as a result of a Market Change" which would excuse payment.

Payments were made by Shionogi through 2016. In 2017 Shionogi notified Summers that Sklice, a prescription product for treating head lice introduced in 2012, met all the requirements for a Market Change within the meaning of the APA as of at least 2015 and that accordingly no further payments were owing.

Summers asserts that there was no Market Change, as defined in the APA, and seeks damages for all remaining payments due from Shionogi pursuant to the terms of the APA. Summers further asserts that even if there was a Market Change the failure to meet the minimum sales specified in the APA was not the result of the Market Change as is also required by the

[1] As the successor in interest, Tr. Zoltan 359, 421, all references to Shionogi include Sciele.

APA to relieve Shionogi of its minimum payment obligation. Shionogi, in turn, claims that in view of the Market Change it did not owe Summers a minimum payment, but only a 15% royalty on actual Net Sales ($258, 837). Thus, because Shionogi paid Summers $3 million in earn out payments for 2016, it requests a refund of $2,741,163 plus interest and a declaratory judgment that a Market Change had occurred.

III. PROCEDURAL HISTORY

A. Initial Proceedings

Summers filed its Demand for Arbitration dated July 28, 2017. Shionogi filed its Answering Statement and Counterclaims dated August 30, 2017. Summers filed its Answering Statement to Shionogi's Affirmative Defenses and Counterclaims dated September 29, 2017. Shionogi filed its Amended Answering Statement and Counterclaims dated January 16, 2018.

The Panel has jurisdiction over this dispute pursuant to the parties' agreement to arbitrate set forth in Section 8.5 of the APA, which provides that "any dispute, controversy or claim arising out of or relating to this Agreement, including, without limitation, disputes relating to (a) the validity, inducement or breach or the interpretation of any provision of this agreement, or (b) the interpretation or application of law, shall be decided by arbitration."

Pursuant to Order No. 1 dated January 22, 2018 the schedule and procedures for the arbitration were established. The parties agreed that the Federal Arbitration Act and the laws of the State of New York apply to this arbitration. The parties further agreed that the American Arbitration Association's Commercial Arbitration rules, effective as of October 1, 2013 as supplemented by the Procedures for Large, Complex Commercial Disputes, would govern the procedures for the arbitration. An agreed protective order was entered.

The parties confirmed that the claims asserted by Summers and the counterclaims asserted by Shionogi are arbitrable and subject to the jurisdiction of this Panel.

The undersigned were appointed as arbitrators in accordance with the arbitration agreement.[2]

B. The Joinder Application

Shionogi's initial Answering Statement named as counterclaimants against Summers not only Shionogi but also Concordia Pharmaceuticals, Inc., S.A.R.L. ("Concordia"), Lachlan Pharmaceuticals ("Lachlan") and Zylera Pharmaceuticals, LLC (Zylera"). These entities have successively assumed various responsibilities for marketing, distribution and sales of Ulesfia in the United States. On Summers' application, the United States District Court for the Middle District of North Carolina found that Summers could not be compelled to arbitrate with Concordia, Lachlan and Zylera and issued an injunction prohibiting those entities "from interfering or bringing direct claims again Summers" in the arbitration. Following the court's decision Shionogi filed an Amended Answering Statement listing those entities as "interested parties" and filed an application for joinder here seeking to have those entities joined in this arbitration and, in the alternative, seeking to allow them access to all aspects of the arbitration proceeding. Summers opposed the application.

By Order No. 2 dated March 14, 2018, the Panel denied both aspects of Shionogi's application. The Panel found that there was no authority to support joinder on the facts presented here. The Panel further found that there was no authority that would authorize it to

[2] Judge Shira Scheindlin was substituted as an arbitrator shortly after the commencement of the proceedings following a recusal by the arbitrator initially appointed who developed a conflict upon switching firms.

allow a nonparty access to the arbitration's private and confidential process. Shionogi was advised that, of course, it was "at liberty to present representatives of Concordia, Lachlan and Zylera as witnesses, to confer with them about strategy, and to provide its own documents and trial preparation materials to those entities insofar as the materials do not divulge Summers' submissions or Summers' documents."

C. Document Exchange and Evidentiary Disputes

Several issues relating to document exchange and evidentiary matters arose in the course of the arbitration, the Panel: (a) declined to compel production of communications between Shionogi and Zylera, Lachlan and Concordia finding that Shionogi had satisfied all of the requirements for the application of the common interest doctrine; (b) ordered the appearances of certain witnesses for a hearing; (c) denied Summers' *in limine* motion seeking to preclude parol evidence pertaining to the language in the APA but reserved decision "as to whether extrinsic and parol evidence will be considered in its [the Panel's] review of the issues presented;" and (d) denied Summers' *in limine* motion seeking to preclude certain testimony by Shionogi's expert but noted that "the construction of disputed terms in the contract is the province of the Panel and testimony by an expert that usurps that role will be disregarded."

The hearing was conducted in New York, N.Y. on July 23-27, 2018 at the American Arbitration Association, 150 E. 42nd St. 17th Floor.

Claimant submitted the following witness statements and expert reports:

- Michael J. Precopio, President and Chief Executive Officer of Summers
- Expert witness Dr. Jeffrey Bomze, a board-certified pediatrician
- Expert witness Gregory K. Bell, Ph.D., Group Vice President at Charles River Associates, an economics and management consulting firm

Respondent submitted the following witness statements and expert reports:

- Andrew Zoltan, Vice President of IP and litigation for Shionogi
- Edward J. Schutter, CEO of Arbor Pharmaceuticals formerly President of Shionogi, USA and before that of Sciele
- Robert D. Ford, Managing Director and Senior Director, Legal Affairs at Concordia
- Robert C. Moscato, Jr., co-owner of Zylera until its purchase by Cerecor Inc. ("Cerecor")
- Expert report of Richard J. Pollack, Ph.D., a public health entomologist
- Expert report of Dr. Bernard A. Cohen, a pediatric dermatologist
- Expert report of Brian C. Reisetter, RPH, M.B.A., Ph.D., President and Owner of Reisetter Health Services, Inc., a privately owned consulting firm

All witnesses who had submitted witness statements were presented at the hearing and were cross-examined. The parties also presented the video deposition excerpts of Edward Boylan, Brand Manager for Ulesfia at Zylera now employed by Cerecor, and Mr. Boylan appeared live by video.

Extensive pre-hearing and post-hearing (see Order No. 10) briefing was submitted by the parties and numerous exhibits were introduced and admitted.

Following the submission of post-hearing briefs, the Panel held an in-person argument on August 24, 2018 with respect to the claims and counterclaims. At the Panel's request, the parties filed submissions with respect to applicable interest rates on September 7, 2018 and September 14, 2018 respectively.

IV. BACKGROUND FACTS

The Panel has received and considered extensive evidence presented by the parties concerning the factual background of this dispute. All of this evidence has been taken into account in reaching the Panel's ultimate conclusions. The following statement of facts mentions some of the salient events to provide context for this Award and reflects certain undisputed facts, certain facts found by the Panel based on the evidence and certain contentions of the parties. It is

not intended to represent a comprehensive or complete narrative of all of the information that the Panel has considered and evaluated.

A. Head Lice Treatments Prior to Ulesfia

Head lice are small grayish-white parasitic insects that live on the human scalp and feed on blood. Each year, about 6-12 million lice infestations occur among 3 to 11 year olds in the U.S. Female lice deposit their eggs, called "nits," in the infested patient's hair; the nits later hatch and grow into adult lice. Head lice infestations can be stigmatizing to children and a major source of parental anxiety. Because children are often barred from school or day care during the infestation period, head lice infestation can cause loss of income for parents and absenteeism from school for children.

Historically, people resorted to soaps and lotions formulated with toxic substances, including DDT, to battle head lice. Head lice can be and is treated (with varying degrees of efficacy and safety) in any number of ways which include not only prescription ("Rx") products and pharmaceutical Over the Counter ("OTC") products but also a variety of methods which include (a) "home remedies" such as applying oils and liquids such as mayonnaise, olive oil, diluted vinegar, gasoline or kerosene on the head; (b) manual removal with lice combs also known as nit combs, Robi Comb or Licemeister or at delousing clinics; (c) homeopathic products like Lice Guard, Lice Arrest, Lice Off, Lice Off Oil or Lice Out; (d) heat application with a lice buster hair dryer; and (e) head shaving. Exhibit 109, at 26, 31.

Beginning in the 1970s, OTC medications for treating head lice emerged containing permethrin and pyrethrins which have insecticidal activity against a broad array of insects. OTC products formulated with these ingredients include RID and NIX, the largest selling OTC drug products for lice. While OTC products can be obtained easily, inexpensively and quickly

without a prescription, the effectiveness of these medications has diminished since their introduction. U.S. government data demonstrates rapidly rising resistance in the U.S. with 42 states reporting resistance.

At the time of the APA's negotiation, the Rx market consisted of only two products (and their generic versions): Ovide (malathion) and Kwell (lindane). Malathion is flammable, and must be left on the hair for 8 to 12 hours. The product using it, Ovide, is cosmetically unacceptable, malodorous, and not approved for use in children less than 6 years of age. Lindane "had a black box warning," was not approved for children or the elderly, was only approved for those who weigh over 120 pounds, can cause seizures, and was banned in California.

B. Summers' Development of the Invention

Summers is a family-owned and operated dermatological product company in Pennsylvania founded in 1986. Summers maintains 15 separate product lines, all topical liquid or semiliquid products. Mr. Precopio, the president and chief executive officer, invented and patented a series of water dispersible, substantially air impermeable liquid barriers for the topical treatment of ectoparasites such as head lice, by asphyxiation, which are water-soluble and therefore easily removed from the hair. Mr. Procopio's invention was patented in the United States. Exhibit 182. The invention asphyxiates ectoparasites by effectively preventing the ectoparasites from closing their respiratory system.

Summers filed a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"). The FDA approved Ulesfia for sale solely as a Rx product in the United States. Summers did not apply for patents in Mexico or Canada.

C. The Asset Purchase Agreement

Shionogi became interested in the patented invention in 2007 based on its safety profile and lack of neurotoxicity. The other pharmaceutical products available at that time for the treatment of head lice functioned by poisoning or otherwise attacking the nerve cells of head lice such that they functioned as neurotoxins. Summers' invention was different. *See,* Exhibit 194 Shionogi 8-K announcing the acquisition dated July 16, 2007.

Negotiations commenced in May 2007. Summers and Sciele executed the APA on July 16, 2017. Exhibit 1. The APA was negotiated between sophisticated parties with highly experienced counsel with Morgan Lewis & Bockius LLP representing Summers and Paul Hastings LLP representing Sciele.

Under the APA, Summers sold to Shionogi all assets and rights needed to develop, manufacture, and market the Product (*i.e.*, a water-dispersible lice asphyxiating product for the topical treatment of head lice) in the Territory, which the APA defines as the United States, Canada, and Mexico. APA § 2.1. In return, Shionogi promised to pay Summers a Purchase Price of (a) $2 million in an Upfront Payment (b) Deferred Payments upon the achievement of certain milestones (*e.g.*, a combined $18 million for NDA acceptance, submission of studies and NDA approval); and (c) a yearly earn out with a minimum payment through January 1, 2022, the "Exclusivity Period"[3] as described in further detail below. *See* APA § 2.6. Because Shionogi

[3] The termination date of the "Exclusivity Period" was definitively set by the First Amendment to the APA. Exhibit 2.

will continue to owe Summers quarterly payments on Net Sales of Ulesfia as an OTC product after January 1, 2022, those payments are not covered by the Exclusivity Period. APA § 2.6(b)(v)(3).

Beginning after the third calendar year,[4] if the Net Sales achieved each year do not equal $20 million, Shionogi is obligated to pay the difference between the amount owed as a percentage of actual sales[5] and the amount that would be paid for that year based on net sales of $20 million (an annual Minimum Payment of $3 million). APA §§ 2.6(b)(v)(1) and 2.6(b)(v)(2). Shionogi is not obligated to make the $3 million Minimum Payment if: (1) it makes more than $20 million in annual Net Sales; or (2) a Market Change occurs but the yearly Net Sales of the Product did not fall below $20 million for reasons "other than as a result of a Market Change." APA § 2.6(b)(v)(2).

Section 2.6(b)(v)(2) of the APA provides:

> Minimums: In the event that, upon the conclusion of a calendar year following Regulatory Approval and during the Exclusivity Period, *and other than as a result of a Market Change*, the annual Net Sales of the Product (excluding sales of the OTC Product) are less than the amount listed for such particular calendar year below, then Buyer shall pay within thirty (30) days of the conclusion of such calendar year by immediately available funds the difference between (x) the amounts paid to date for such year based on the percentage of the Net Sales actually existing and the (y) amounts that would be paid to date for such year based on the percentage of Net Sales listed alongside each calendar year below… (emphasis added).

Section 1.24 of the APA defines Market Change as follows:

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[4] The parties are in agreement that the third year had been reached prior to 2016 since the first commercial sale was in 2009.

[5] The APA called for payment of 15% on annual net sales of $20-50 million and increasing percentages for greater sales. APA §§ 2.6(b)(v)(1).

> "Market Change" means a market or environmental condition which (a) reduces the incidents of head lice by more than ninety percent (90%) in the Territory or (b) significantly alters or changes the method of treatment of head lice and which results in a single Third Party acquiring greater than forty percent (40%) market share for the treatment of head lice.

D. Shionogi's Development of Ulesfia and Ulesfia Sales

Shionogi developed Ulesfia from the rights it had purchased from Summers. Ulesfia is the only product that Shionogi developed from the assets it purchased through the APA. Ulesfia is formulated as a 5% benzyl alcohol (active ingredient) topical lotion and is labeled for use on infants older than 6 months of age to adults. Benzyl alcohol causes the spiracles (breathing pores) of lice to remain open and become obstructed by other ingredients within the formulation, resulting in death of lice by asphyxiation. But benzyl alcohol has no effect on unhatched lice eggs (ova) so achieving eradication of head lice from the scalp using Ulesfia requires a second treatment with Ulesfia seven to ten days after the first. Ulesfia also requires that the hair be saturated often resulting in the need to purchase multiple bottles for longer hair.

Ulesfia was only sold in the United States. Although Concordia obtained approval to sell Ulesfia as an OTC product in Canada, none of the companies which were responsible for the sale of Ulesfia over the years attempted to sell Ulesfia in Canada or Mexico where there was no patent protection.

E. New Market Entrants – Rx and OTC Pharmaceutical Products

In 2011, Natroba, using spinosad as the active agent, was commercialized as an Rx product for the treatment of head lice.

In 2012, Sklice, using topical ivermectin as the active agent, was commercialized as an Rx product for the treatment of head lice. Based on sales of Sklice, Shionogi claims that a

Market Change occurred within the meaning of the APA. This is the central focus of the dispute before the Panel.

It is undisputed that pharmaceutical OTC products, including NIX and RID which dominate the sales of those products, account for the majority of unit sales of the entire market for the drug treatment of head lice. At the time of the APA, the parties estimated the market as $500,000 for Rx and $6,850,000 for OTC. Exhibit 108 slides 7– 8; *see also* Tr. Moscato 1393-1394. That OTC pharmaceutical product sales have commanded the great majority of the total pharmaceutical lice treatment market has been true since the execution of the APA, and remains true today. Tr. Precopio 208-209 (estimating today's respective market sizes).

F. Ulesfia Is Transferred from Shionogi to Concordia to Lachlan to Zylera to Cerecor

Prior to Ulesfia's April 2009 FDA approval, Shionogi acquired Sciele. A few years later Shionogi refocused its business strategy. As a result, Ulesfia, principally a pediatrics product, no longer fit its business plan. Shionogi granted an exclusive license to Concordia on May 6, 2013 for the marketing and sale of Ulesfia in the United States, Canada, and Mexico. Exhibit 28. Eight months later, on January 1, 2014, Concordia entered into an agreement with Lachlan transferring an exclusive license to market Ulesfia only in the United States. Exhibit 29. On the same date, Lachlan and Zylera entered into an Exclusive Wholesale Distribution Agreement, by which Zylera became the exclusive marketer of Ulesfia in the United States. Exhibit 312.

In November 2017, Cerecor acquired Zylera and the exclusive distribution rights for Ulesfia in the United States, along with rights to Zylera's other products. Exhibit 4. The Cerecor agreement contemplates the development of a product "New Ulesfia"—an FDA-approved Ulesfia® (Benzyl alcohol) Lotion having a unique form and/or strength as compared to the

currently marketed product. *Id*. at 2744. The agreement provides for a $4 million incentive payment to Robert Moscato and Randal Jones, the prior owners of Zylera, for: (i) obtaining the transfer of the Ulesfia NDA to Cerecor; and (ii) the approval by the FDA of New Ulesfia.

G. Sales and Marketing of Ulesfia

It is undisputed that Shionogi failed to achieve the Net Sales minimums under APA §2.6(b)(v)(2) against which payments were to be calculated in any year after 2010. While Ulesfia failed to achieve the Net Sales minimums, between 2011 and January 2014 Ulesfia did capture between 23% and 32% of the sales for Rx products for the treatment of head lice. Bell Rebuttal Report Exhibit C-3; Zylera Market Share Analysis Exhibit 15. After January 2014, with Zylera in control, Ulesfia sales dropped to around 10% of the Rx U.S. sales for the treatment of head lice after one year, and to around 1% after three years. During that time, sales of both Natroba and Sklice grew. Exhibit 15. Ulesfia sales even dropped below those of Lindane, a lice treatment product that was universally considered to be a dangerous product. *See* Lindane Package Label Exhibit 48; Tr. Cohen 802; Tr. Bomze 578-579.

Summers asserts that Zylera did not support the product with adequate resources, that Zylera's sole brand plan was devoid of sales goals, forecasts and budgets for marketing activities, and Zylera had no territory representatives in major metropolitan areas. Summers further asserts that the pricing strategy used for Ulesfia had a significant and negative impact on Ulesfia's performance in the Medicaid market and as a consequence on overall sales due to the "spillover effect" as doctors tend to prescribe a single product whether for Medicaid or private insurance coverage. At launch, Shionogi set Ulesfia's Average Wholesale Price ("AWP") at $61.02 per unit. Shionogi and Concordia adjusted Ulesfia's price modestly over the course of the next few years. During its management of the product Zylera increased the price of Ulesfia

from $180 to $435.14, not including any discounts or coupons offered. The pricing of Ulesfia over the years made Medicaid sales unprofitable. The Panel notes that it costs Lachlan $10 to manufacture a unit of Ulesfia. Tr. Moscato 1409. Zylera is contractually obligated to pay Lachlan $58.84 per unit of product plus a percentage of prior year's sales.

H. Payments, APA Amendment and Notice of a Market Change

In April 2015, Shionogi adopted a new procedure for making prorated quarterly payments of $750,000 to Summers as opposed to year end payments based on actual net sales and any minimum payment owed for the year. Payments were made on this basis throughout 2016.

Shionogi negotiated a First Amendment to the APA with Summers, which was executed on March 16, 2017. Exhibit 2. The First Amendment reaffirms Shionogi's payment obligations under the APA,[6] permits Shionogi to license certain Ulesfia assets to Concordia, and establishes January 1, 2022 as the end of the Exclusivity Period.

On December 9, 2016, Zylera notified Lachlan by email of the purported Market Change. On December 21, 2016, Lachlan notified Concordia by email of the purported Market Change. On January 17, 2017, Concordia notified Shionogi by email of the purported Market Change. Although Shionogi was on notice of the purported Market Change as of January 2017, Shionogi never raised this with Summers during the negotiations for the Amendment to the APA. On June 12, 2017, Shionogi notified Summers that a Market Change had occurred, stating that "since at

[6] Section 2 of the Amendment provides: "For clarity, all obligations of Shionogi under the agreement [the APA], including the payment of all monies owed, due or payable to the Company [Summers] thereunder, shall remain obligations of Shionogi and shall not become the obligations of Concordia or any other party as a result of the foregoing consent…"

least December 2015 at the latest…, Arbor Pharmaceuticals' Sklice ® (ivermectin) lotion 0.5% ("Sklice") has acquired more than 40% of the market share for the treatment of head lice in the United States." Exhibit 173. Shionogi demanded return of $2,741,163, which Shionogi claimed it had overpaid in 2016.

Summers initiated this arbitration in August 2017 to protect its rights to the minimum payments under the APA. Shionogi counterclaimed for the return of the funds it had paid for 2016 and sought a declaratory judgment as to the occurrence of a Market Change.

V. THE ISSUES

1. Did a Market Change occur within the meaning of Section 1.24(b) of the APA?
    a. What is the territorial market in which the market for the treatment of head lice should be measured?
    b. What is the product market in which the market for the treatment of head lice should be measured?
    c. Did Sklice achieve a 40% market share for the treatment of head lice in the relevant market?
    d. If Sklice achieved a 40% market share for the treatment of head lice in the relevant market did it "significantly alter or change the method of treatment of head lice?"
2. If a Market Change occurred within the meaning of Section 1.24(b) of the APA, was the failure to achieve the target Net Sales specified in the APA caused by something "other than as a result of a Market Change" as required pursuant to APA § 2.6(b)(v)(2)?

3. If a Market Change occurred, is Shionogi entitled to a return of $2,741,163, the sum it paid Summers in 2016 in excess of the percentage owed pursuant to APA § 2.6(b)(v)(2) on actual Net Sales?
4. If a Market Change within the meaning of Section 1.24(b) of the APA did not occur and Shionogi's obligation to make the minimum payments continued, what damages should be awarded to Summers?
    a. In what amount and for what year(s) should damages be awarded to Summers?
    b. Is Summers entitled to an acceleration of future payments that might be due through January 2022 under the Guaranty Agreement?
    c. What interest rate is applicable to any damages and as of what date should interest run?
5. Should attorneys' fees and costs be awarded to any party, on what basis, and in what amount?

VI. ANALYSIS

We begin with the question of whether a Market Change as defined in Section 1.24(b) of the APA occurred with the introduction of Sklice in determining whether Shionogi continued to have obligations to make the minimum payments.

A. Burden of Proof

The parties differ as to who bears the burden of proof. Summers asserts that Shionogi "has the burden of proving that its obligation to make the Minimum Payment was discharged by the Market Change." Claimant's Post-Hrg. Br. at 16. Shionogi takes the position that "as the primary claimant in this action, Summers bears the burden of proof." Respondent's Post-Hrg. Br.

at 1. The Panel concludes that Summers has the burden of proving the contract's existence and validity and that the minimum payments were not made. Shionogi has the burden of proving Market Change. Upon such proof, the Panel would turn to whether the failure to achieve the minimum sales was "other than as a result of a Market Change."

There is no dispute as to the existence or validity of the APA and there is no dispute that Shionogi did not make the minimum payments for 2017. Tr. Precopio 68-69. Thus, Summers has met its burden of proof on those issues.

While Shionogi correctly notes that the Claimant has the burden of proving the "existence, terms and validity" of the contract," *see Paz v. Singer Co.*, 542 N.Y.S.2d 10 (1st Dept. 1989), Shionogi Post-Hrg. Br. at 1, Shionogi's assertion of a Market Change as excusing its obligation to make the minimum payments is an affirmative defense that Shionogi must prove.

"An affirmative defense is defined as 'a defendant's assertion raising new facts and arguments that, if true, will defeat the plaintiff's claim, even if all allegations in the complaint are true.'" *Saks v. Franklin Covey Co.*, 316 F.3d 337, 350 (2d Cir. 2003), *quoting* Black's Law Dictionary 430 (7th ed. 1999) and citing *Wolf v. Reliance Standard Life Ins. Co.*, 71 F.3d 444, 449 (1st Cir. 1995) (the test for whether a defense must be pleaded as an affirmative defense is whether the defense "shares the common characteristic of a bar to the right of recovery even if the general complaint were more or less admitted to"). Thus Shionogi correctly pleaded as affirmative defenses that "Summers' claims are barred, in whole or in part, by the express terms of the APA and First Amendment" and "specifically pleads all terms of the APA and First Amendment… Summers reserves the right to raise such additional affirmative defenses as may

be established during discovery and by the evidence in this case." Respondent's Amended Answering Statement at 2.

Under New York law, the defendant has the burden of establishing facts sufficient to support an affirmative defense. *Barton Gp., Inc. v. NCR Corp.*, 796 F. Supp. 2d 473, 498 (S.D.N.Y. 2011), *aff'd*, 476 Fed. Appx. 275 (2d Cir. 2012). Here a Market Change, if it occurs, relieves Shionogi of the minimum payment obligation and defeats Summers' claim (subject to proof as to whether the failure to meet minimum was other than as a result of the Market Change) and as such constitutes an affirmative defense on which Shionogi has the burden of proof.

Summers argues in the alternative that the Market Change provision is a condition subsequent on which Shionogi bears the burden of proof. The Panel agrees. "A condition subsequent is one that, if it arises, will defeat an existing obligation." 22 N.Y. Jur. 2d Contracts § 258. Upon the execution of the APA and the transfer to Shionogi of the rights to develop Ulesfia, Shionogi became responsible for the minimum payments. That obligation was in place unless and until a Market Change, the "condition subsequent," occurred. Here as in *Mereminsky v. Mereminsky*, 188 N.Y.S.2d 771 (2d Dept. 1959): "Defendant was obligated to make the payments agreed upon. The conditions set forth in [the Market Change condition] are in the nature of escape clauses, providing that the defendant's liability to make the payments would cease in the event that certain things should occur." The court held that because the condition was a condition subsequent the burden of proof rests with the defendant. *Accord* Modern Law of Contracts § 10:3 ("[T]he defendant has the burden for a condition subsequent."); *Rachmani Corp. v. 9 E. 96th St. Apt. Corp.*, 211 A.D.2d 262, 270 (1st Dept. 1995) ("The party burdened by

the [contractual obligation] . . . has the burden of proving the discharge of his duty by the occurrence of a condition subsequent.").

As the court noted in *Mereminsky* a different approach would mean that defendant "could cease making these payments whenever and as often is it suited him to do so, and each time the plaintiff sought to recover, the burden would be thrown upon the" plaintiff to establish the condition subsequent. *Mereminsky,* 188 N.Y.S.2d at 777. The legal principle that the burden of proof on a condition subsequent is on the defendant is particularly compelling here as all the information about the product and the sales of products for the treatment of head lice are possessed by Shionogi and its successors who were marketing and selling Ulesfia and not in the hands of Summers.

B. Principles of Contract Construction

It is Summers' position that the market change definition in the APA is "clear and unambiguous on its face." Claimant's Post-Hrg. Br. at 39. Throughout these proceedings Shionogi has consistently taken the same position. *See* Respondent's Pre-Hrg.Br. at 21("there is no ambiguity"). In its post-hearing submission, Shionogi appeared to diverge from that position and introduced extrinsic evidence in support of its position, but at the post-hearing argument confirmed that it was of the view that there is no ambiguity but added that the Panel could nonetheless consider parol evidence to determine whether any construction based on the plain language of the APA was absurd or commercially unreasonable, or contrary to the reasonable expectations of the parties. Tr. Perloff 1717-1718.

Whether an agreement is ambiguous is a question of law. *Law Debenture Tr. Co. of New York v. Maverick Tube Corp*. 595 F.3d 458, 465-467 (2d Cir. 2010). Ambiguity is determined by

looking solely at the text of the document, not to outside sources. *Riverside S. Planning Corp. v. CRP/Extell Riverside, L.P.*, 13 N.Y.3d 398, 403 (2009).

The Panel agrees with the parties and finds that the APA, including Section 1.24, the Market Change definition, is unambiguous. "The best evidence of what parties to a written agreement intend is what they say in their writing." *Cytec Indus., Inc. v. Allnex (Luxembourg) & Cy S.C.A.*, No. 14-1561, 2017 WL 2634177, at *5 (S.D.N.Y. June 19, 2017). The APA is an arm's-length agreement between highly sophisticated parties represented by experienced counsel. The language of the APA, and in particular the Market Change definition, was carefully considered and negotiated. The Market Change definition itself was addressed and revised in no less than four drafts. *See, e.g.*, Exhibits 61,166,167,168,169. The Panel looks to the unambiguous provisions of the APA in making its decision.

"Where the terms of the contract are clear and unambiguous, the intent of the parties must be found within the four corners of the contract, giving a practical interpretation to the language employed and reading the contract as a whole." *Cytec Indus., Inc.* 2017 WL 2634177, at *5. In construing an unambiguous contract the entire contract must be reviewed and "[p]articular words should be considered, not as if isolated from the context, but in the light of the obligation as a whole and the intention of the parties as manifested thereby. Form should not prevail over substance and a sensible meaning of words should be sought." *Riverside S. Planning Corp.*, 13 N.Y.3d at 398 (citations omitted). The contract should not be interpreted to produce a result that is "absurd" or "commercially unreasonable." *Luver Plumbing & Heating, Inc. v. Mo's Plumbing & Heating*, 43 N.Y.S.3d 267, 269 (1st Dept. 2016). The clauses of a contract should be read together contextually in order to give them meaning. *HSBC Bank USA v. Nat'l Equity Corp.*, 719 N.Y.S.2d 20, 22 (1st Dept. 2001); *see also Nash v. Gay Apparel Corp.*, 193 N.Y.S.2d 246,

249 (1st Dept. 1959) ("The complete instrument with all its contextual meanings in 'the light of the obligation as a whole' is the main guide to construction."). The Panel applies these contract construction principles in reviewing the APA.

C. The Territorial Scope of the Market

The parties dispute the countries that make up the relevant market.[7] Summers contends that the relevant market for purposes of determining whether a Market Change had occurred is the "single market, which covers all of the United States, Canada and Mexico." Claimant's Post-Hrg. Br. at 46-47. Shionogi claims that the market for the treatment of head lice refers only to the United States. Respondent's Post-Hrg. Br. at 34-37.

The language of the Market Change provision supports Shionogi's position. "Territory" is defined in the APA as including the United States, Canada and Mexico. Subparagraph (a) of Section 1.24 of the APA applies where there is a reduction in "the incidents of head lice by more than ninety percent (90%) in the Territory," that is, in the U.S., Canada, and Mexico. By contrast, subparagraph (b) of Section 1.24 of the APA applies when a new product enters the market and "results in a single Third Party acquiring greater than forty percent (40%) market share for the treatment of head lice." Because the term "Territory" is specifically used in subparagraph (a) and *not* in subparagraph (b), it presumptively does not apply to this separate clause. "Under accepted canons of contract construction, when certain language is omitted from a provision but placed in other provisions, it must be assumed that the omission was intentional."

[7] Section 1.24(a) is not in dispute in this proceeding.

Sterling Investor Servs., Inc. v. 1155 Nobo Assoc., LLC, 818 N.Y.S.2d 513, 516 (2d Dept. 2006) (citation omitted).

Moreover, the business reality in the context in which this contract must be construed similarly supports this outcome. There is no realistic means to compare data across national boundaries for lice treatments. Tr. Reisetter 1206. Requiring a review of market share in the U.S., Canada and Mexico combined would not be commercially reasonable in the circumstances.

The Panel FINDS that the territory in which the market and sales requirements of subparagraph (b) of Section 1.24 of the APA must be assessed is limited to the United States.

D. The Scope of the Product Market

Summers contends that the "market … for the treatment of head lice" as specified in Section 1.24(b) of the APA, the Market Change definition, includes both "OTC and prescription product sales." Claimant's Post-Hrg. Br. at 40-47. Shionogi claims that the market for the treatment of head lice "refers only to the prescription market." Respondent's Post-Hrg. Br. at 20-34.

Assessing the scope of the product market from the perspective of (a) how the various lice treatment products are actually sold and marketed; (b) a reading of the contract sensibly as a whole, and (c) commercial reasonableness, the Panel concludes that the "market … for the treatment of head lice" for purposes of Section 1.24(b) of the APA is limited to the Rx market**.**

First, even if we were to look only at the pharmaceutical OTC products for the treatment of head lice, like NIX and RID, which are most similar to Rx products as both of these OTC

products and the Rx products are pharmaceuticals, we must nonetheless conclude that the forty percent (40%) market share for the treatment of head lice relates solely to the Rx market.

OTC drugs are much cheaper than Rx drugs. Tr. Precopio 115. Pharmaceutical OTC head lice products are priced at about one-tenth to one-fortieth of the price of Rx head lice products. Tr. Reisetter 1262-1263, 1200-1201. Generally products that are prescribed by physicians are covered by insurance but head lice products not purchased pursuant to a prescription are not covered. Tr. Precopio 116, 120; Tr. Reisetter 1203. Prescription drugs are marketed—"detailed"—to doctors with direct sales efforts; OTC products are not. Tr. Bomze 635; Tr. Precopio 120. The patient or the parent alone decides which OTC product to buy at the retail establishment. Tr. Reisetter 1302**.** If the patient chooses to see a doctor, it is the physician who decides which product should be prescribed. Tr. Reisetter, 1198, 1302; Tr. Bomze 581-583. A drug can only be approved by the FDA as a prescription drug *or* an OTC drug; it cannot be both at the same time. Tr. Bell 1038-1039; Tr. Schutter 1136. When it entered into the APA, Sciele was exclusively in the Rx market with all of its products and from the beginning Ulesfia was only an RX product and could not be sold OTC without additional governmental approvals. Tr. Schutter 1119-1120; Tr. Moscato 1496-1497; Tr. Precopio 118. Pharmaceutical companies that sell Rx drugs that later switch to OTC typically have a different division handle their commercial sales "because it's treated more like Tylenol and toothpaste than it is a drug at that point." Tr. Reisetter 1201. *See generally* Reisetter witness statement ¶¶ 22 – 31.

Thus, as a matter of the realities of the marketplace, Rx and OTC products compete differently with completely different pricing, a different target audience, and different marketing all of which support the conclusion that Rx products and OTC products for the treatment of head

lice comprise different markets.[8]

Considering the language of the APA as a whole further supports the conclusion that the market for purposes of Section 1.24(b) includes only the Rx market. The APA contains separate definitions of the OTC Market, OTC Product and OTC Revenue. APA §§1.27, 1.28, 1.29. None of these defined terms is included in the definition of Market Change. The definition of OTC Market in the APA defines two separate markets – an "over-the-counter, non-prescription market" as opposed to "prescription sales." This demarcation of the two markets is also reflected in other provisions of the APA. For example, the APA *excludes* OTC sales from the calculation of Net Sales used to determine whether a minimum payment is triggered by Section 2.6(b)(v)(2) of the APA. Payments for sales of OTC Products are separately provided in Section 2.6 (b)(v)(3). The only way to reconcile Section 1.24(b) with Sections 2.6(b)(v)(2) and 2.6 (b)(v)(3)

[8] Both parties rely on presentations made during the negotiation of the APA. Shionogi references a document in which Summers refers to "The Head Lice Market" and states the "Rx Market – approximately $50MM" suggesting Rx is a separate market. *See, e.g.*, Exhibit 108 at slide 7. Summers references a document in which Shionogi refers to the "Lice Market Overview" and in looking at the market size for pesticides for treatment of head lice includes both Rx and OTC products suggesting it is a single market. *See, e.g.*, Exhibit 109 at 26. In the context of the evidence presented, the Panel understands those documents to mean exactly what is stated in the later pages of that same Summers presentation – the OTC market, as it states, provides the "potential" for capturing additional Rx sales (*e.g.*, Ulesfia) with the OTC products as the pool from which the Rx market could be grown. Exhibit 108 at slides 8-9. Summers also emphasized that at one time Zylera was considering putting point-of-sale advertising in the OTC section of the retailer. Exhibit 49. The Panel views this as an effort to tap into the "potential" and not evidence that Rx and OTC are the same product market for purposes of Section 1.24(b) of the APA.

of the APA is to recognize that the "market" for purposes of the Section 1.24(b) means the Rx market, and not the separately defined and addressed OTC market.[9]

Finally, Summers fails to identify what products should be included in its calculation of "OTC product sales." Nonetheless, it argues that "OTC product sales" should be included in the definition of the relevant market. Claimant's Post-Hrg. Br. at 40-47. Summers avoids the issue of identification by suggesting the Panel look at the relevant product market as "just prescription products and just branded and generic NIX and RID topical OTC products in the United States only (a highly conservative approach favorable to Shionogi)." Summers then suggests that if one includes the remaining OTC sales it would "further dilute Sklice's market share." Claimant's Post-Hrg. Br. at 38.

As discussed above, head lice can be and is treated in any number of ways which include not only Rx products and pharmaceutical OTC products like RID and NIX but also widely diverging methods which include oils and liquids, manual removal tools, homeopathic products, and home remedies. Exhibit 109 at slides 26, 31. It is in the context of this panoply of treatments that the issue of the product scope of the market must be assessed. All of these products fall within the APA's definition of "OTC Market" which is defined as "the over-the-counter, non-prescription market, as opposed to prescription sales." APA § 1.27.

[9] Because of the disparate sizes of the OTC and Rx markets, even if a company garnered 100% of the Rx market it would only make up a very small fraction of the unit sales of the head lice drug treatment market. If the Market Change provision required a single market of Rx and OTC, measured in units, no Rx company could ever gain 40% of the market. This is a commercially unreasonable interpretation of the contract.

Shionogi argues, and the Panel agrees, construing the product market for purposes of the market definition to include all nonprescription sales would lead to an "absurd" outcome and would not be commercially reasonable. All of the various remedies for the treatment of head lice (with the exception of the Rx products), are available over-the-counter without a prescription. If the "market for the treatment of head lice" were to be construed to include any and all methods utilized and available without a prescription there would be no way to identify sales or to analyze market share. Tr. Moscato 1497-1498; Tr. Reisetter 1199-2000 ("there is no ability to be able to figure out what those [OTC] numbers are to begin with"). But the Panel need not rely on Mr. Moscato's and Mr. Reisetter's testimony alone to establish that such a construction would not be commercially reasonable because data-based evidence introduced by the parties established that Mr. Moscato correctly testified that measuring the market and market shares would not be possible if all head lice treatments methods were included.

While both parties agreed that reliable data provided by IMS and Symphony is available for Rx products for the treatment of head lice, this is not the case for OTC products. Exhibit 379 is IRI data introduced by Summers to identify market share if one were to just add RID and NIX sales. Counsel for Summers offered an explanation of the IRI data and Shionogi responded but no witness was presented to address the validity or scope of the IRI data. Summers Statement of Facts on Hearing as to Exhibit 379 and IRI Data dated August 3, 2018; Shionogi Response submitted August 6, 2018. Based on counsel's explanations it appears that the IRI data is drawn from point-of-sale scanner SKU readings but only from retailers who voluntarily cooperate with IRI. These retailers may constitute less than 50% of the relevant retailers. IRI then manipulates the data to estimate the missing portions of the OTC market, a methodology of questionable validity.

Moreover, and significantly, if one were to look at the IRI data just to include NIX and RID, the dominant pharmaceutical OTC products, that data would not be accurate for measuring "head lice" treatments as required under the APA because NIX and RID are also used for treating lice on other parts of the body. Exhibits 379, 180. Thus, based on the evidence presented, there is no reliable way to measure the market for the treatment of head lice even if it only included Rx products RID and NIX. And if one were to add all of the other head lice treatments there would be no conceivable way to implement the Market Change definition. Indeed, Summers never attempted to offer such a methodology.

Summers' principal argument in support of its product market definition is that the Panel cannot read a limitation into the Market Change definition that it applies to "prescription products only" since that limitation is not found in Section 1.24(b). Claimant's Post-Hrg. Br. at 41-42, citing *Law Debenture Tr. Co. of New York v. Maverick Tube Corp*. 595 F.3d 458, 472 (2d Cir. 2010). But adopting Summers' position would result in the inclusion of unlimited treatment modalities all of which must be considered as part of the market, including homeopathic, oils and liquids, heat, etc. Defining the product market that broadly would lead to a commercially unreasonable outcome which is contrary to market realities and inconsistent with the language of the APA read as a whole.

The Panel FINDS that the product "market… for the treatment of head lice" for which the market share must be determined pursuant to Section 1.24(b) of the APA is limited to Rx products for the treatment of head lice that cannot be purchased over the counter.[10]

[10] Shionogi also argued in support of its position as to the product market definition that the Panel should construe the APA in accordance with the principle of *contra proferentem* (a principle

E. Percentage of Market Share

The parties are in agreement that if the market for purposes of the Market Change is the Rx market in the United States then based on either Symphony or IMS data, Sklice has captured over 40% of the market, whether measured in dollars or units as of 2016. Tr. Bell 1067-1068; Reisetter 1216. Counsel for both Summers and Shionogi confirmed this fact at the post-hearing argument. Tr. Perloff and Huh 1743.

F. Significantly Alters or Changes the Method of Treatment of Head Lice

To constitute a Market Change, a new Rx product must "significantly alter[] or change[] the method of treatment of head lice." APA § 1.24(b). The parties differ in their contentions regarding whether this provision was met by Sklice's entry into the market. Shionogi contends that it was and Summers that it was not. Claimant's Post-Hrg. Br. at 28 – 38: Respondent's Post-Hrg. Br. at 14 – 20. The Panel concludes that it was not.

In support of its contention that Sklice significantly altered or changed the method of treatment for head lice Shionogi references several sources.

Shionogi references the FDA's medical review of Sklice which it highlights identified Sklice as "unique." Exhibit 207 at 8 ("The demonstration of efficacy with a single 10 minute treatment is unique among anti-lice products and will likely improve compliance."). As discussed below, however, the single 10-minute treatment attributed to Sklice is essentially the

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which the Panel would in any case reject given the extensive negotiation and back and forth between the parties as to the specific language of the Market Change definition such that neither party can be said to be the draftsman of that language) and further contending that there was no meeting of the minds on that issue. Because the Panel has concluded based on other factors that Shionogi is correct in limiting the relevant market to the Rx market, the Panel does not consider those contentions and related extrinsic evidence.

same manner of treatment as for Natroba. Furthermore, this FDA review was prepared in 2011 at a time when Natroba was only approved for patients over 4 years of age. The FDA later approved Natroba for patients 6 months and older just like Sklice. Exhibit 42. Thus, the FDA's statement as to Sklice's uniqueness had no applicability to the market in 2015 and thereafter when Shionogi claims there was a Market Change.

Shionogi also cites a New England Journal of Medicine report which concluded that Sklice offered a "novel mode of action." Exhibit 286 at 1693. But Sklice's mode of action is not novel. Shionogi's own internal corporate documents state that Sklice and Natroba have very similar "modes of action." As Shionogi stated, "The mode of action of spinosad is associated with excitation of the insect nervous system … These data indicate that spinosad acts through a unique insecticidal mechanism. This is very similar to how the pending ivermectin topical works." Exhibit 88 at 5210. Shionogi's expert, Dr. Cohen, in his published literature review supported the similarity between Natroba and Sklice modes of action and noted that both products result in the paralysis and subsequent death of the lice. Exhibit 186 at 2268 – 2269.

In any case Section 1.24(b) of the APA does not reference a "mode of action;" it references a "method of treatment." Shionogi counsel confirmed that a different mode of action is not sufficient to satisfy the requirement that the product significantly alter or change "the method of treatment" Tr. Perloff 1744-1747 ("I don't think the fact that a product has a mode of action that is described as unique would in and of itself be enough to describe something different… The fact that it has a novel mode of action I think only tells you that it's likely doing something different from an existing product. ..So I think …the panel should apply or use method of treatment.").

In fact, the only product that has a different method of treatment in the technical sense of how the product attacks the lice is Ulesfia. As Dr. Pollack, Shionogi's expert, testified if you looked at "mode" or "mechanism" of action as a "method" then Sklice, Natroba, RID, NIX, Ovide and Lindane all utilize neurotoxicity as their method of treatment. He confirmed that "the only product with a different mechanism of action is Ulesfia." Tr. Pollack 865 – 866. This is reflected in Summers' patent application which describes its invention by distinguishing it from the "current methods of treatment of ectoparasites, e.g., lice, [which] typically utilize insecticidal compositions which are available in both prescription and over-the-counter formulations." Exhibit 34 at 25712. Ulesfia's invention is described as preventing the ectoparasites from closing their respiratory systems and thus suffocating the lice.[11]

Also, Shionogi has asserted that Sklice is a "significant change or alteration to the method of treatment of head lice" because of its single 10-minute application, good track record for safety, ease of application, cosmetic acceptability, and high efficacy all without requiring the use of a nit comb. Shionogi's Pre-Hrg. Br. at 4, 26- 27. Shionogi's expert, Dr. Cohen, identified what in his view should be reviewed in determining if there was a significant change or alteration in the "method of treatment." He listed "efficacy, safety, ease-of-use, and compliance." Tr. Cohen 883 – 885. He concluded that Sklice met that test. Summers' expert, Dr. Bomze, stated: "To me means something that is going to – in my mind, as a clinician, that is going to have a

[11] Not only is Ulesfia in fact the unique product, but, as was noted as the hearing, because Ulesfia operates by asphyxiation rather than neurotoxicity it is the only product on the market today to which resistance cannot develop. Pollack Tr. 933-934. As Dr. Pollack, explained, "[i]t's hard to imagine how lice would develop some resistance to [asphyxiation]. . . . It's like putting a plastic bag over an animal's head." *Id.* By comparison, Dr. Pollack testified that neither Sklice nor Natroba had experienced resistance yet, but that he "would certainly bet that there will be resistance [against these products] at some point." *Id.* 897-898, 900.

change that will make me recommend that patients accept a different product…Something that is going to make a difference in safety, efficacy, potentially compliance, cost, ease." Tr. Bomze 880-881. He concluded that Sklice did not meet that test.

The evidence does not support Shionogi's conclusion. While Sklice shares many attributes with Ulesfia, RID and NIX as summarized on Demonstrative Exhibit 47, the Panel limits its analysis of the evidence as to whether Sklice significantly changed the method of treatment for head lice by comparing Natroba and Sklice – which are essentially identical with respect to each of these factors.

A comparison of the FDA approved labels for Sklice and Natroba is instructive. Exhibits 41 and 42.

- Both Sklice and Natroba state for "indications and usage:" "Lotion is a pediculicide indicated for the topical treatment of head lice infestations in patients 6 months of age and older."
- Both Sklice and Natroba state that the lotion should be applied to dry hair in an amount to cover the scalp and hair.
- Both Sklice and Natroba state that it should be rinsed off with water after 10 minutes.
- Neither require the use of a nit comb although both state nit combs "may be used to remove dead lice and nits."
- Natroba's label states that the treatment should be repeated "only if live lice are seen 7 days after the first treatment." The Sklice label is silent on that, but the studies show that the efficacy rate of Sklice is essentially the same as Natroba after one application and the need to repeat the treatment because live lice are found a week after treatment is essentially the same for both. Studies reported the Sklice efficacy rate as 71.4% and 76.1% as against Natroba at 68.1% and 75.9%. Dr. Cohen's Literature Review Article Exhibit 186 at 2269. Dr. Cohen confirmed that Sklice fails to successfully treat the patient in one out of four cases after a first application. Tr. Cohen 260. While neither is ovicidal, Tr. Cohen 730, Natroba and Sklice were equally effective and require a second treatment in closely comparable incident numbers.
- With respect to safety, Natroba is labeled category B for use during pregnancy ("should be used during pregnancy only if clearly needed") while Sklice is labeled the more

> cautionary category C ("to be used during pregnancy only if the potential benefit justifies the potential risk to the fetus"). In addressing pediatric use Natroba has an additional caution, stating that benzyl alcohol has been associated with serious adverse reactions in neonates and low birth weight infants due to a "gasping syndrome" which has been associated with benzyl alcohol. While it seems more likely that a pregnant woman would have a child with lice and might require treatment than an infant under the age of 6 months would have lice, the expert testimony presented at the hearing concluded that neither of these risk factors identified in the FDA label was of great significance. Thus, the Panel concludes that Natroba and Sklice do not differ in any material way in terms of safety.

All of the experts presented by the parties agree that Sklice and Natroba are nearly identical topical head lice treatments, each being a: (1) one-time, (2) 10-minute (3) neurotoxic head lice treatments, (4) applied topically to dry hair and rinsed out with water, (5) that do not require a nit comb, and (6) are similar in safety and efficacy. Tr. Bomze 712-715; Tr. Pollack 846-848, 853, 855, 856-858; Dr. Cohen's Literature Review Article Exhibit 186 at 2265, 2268-69.

Dr. Cohen confirmed that Sklice is very similar to other head lice treatments in his literature review, which concluded: "Prescription products shown to be safe and effective with a single application, without nit combing, are topical ivermectin [Sklice], malathion, and spinosad [Natroba], whereas benzyl alcohol [Ulesfia] requires two applications." Exhibit 186 at 2265. Dr. Cohen's literature review article analyzed 579 head lice treatment articles, including the most recent up-to-date literature, to provide a comprehensive analysis. Exhibit 186 at 2266; Tr. Cohen 740-743. The purpose of Dr. Cohen's literature review was to provide "guidelines for pediatricians and providers who were prescribing had lice treatments." *Id.*

Dr. Pollack's testimony summarizes the uniform opinion of all of the experts on the similarities between Natroba and Sklice:

> Q. And Dr. Pollack, talking briefly about Natroba, you are familiar with the properties and attributes of the head lice treatment Natroba?

A. Yes, I am.

Q. And like Sklice, you are aware that Natroba is a topical applicant for the treatment of head lice?
A. Correct.

Q. And like Sklice, you are aware that Natroba is a one-time use product?
A. That is how it is labeled, yes.

Q. And like Sklice, you are aware that Natroba does not require a nit comb?
A. Correct.

Q. And like Sklice, you are aware that Natroba is currently approved for children older than six months of age?
A. That is the current recommendation, although originally I believe it had a limitation of four years of age.

Q. Okay. But you are aware that Natroba, like Sklice, is currently approved for children six months and older?
A. That is the current approval, yes.

Q. And like Sklice, Natroba is also applied to the hair and removed after about ten minutes?
A. That's right.

Q. And like Sklice, Natroba also treats lice through its neurotoxic properties; correct?
A. Yes.

Q. So, like Sklice, Natroba causes neuronal excitation in the head lice, leading to its eventual paralysis and death?
A. That's correct.

Q. Both Natroba and Sklice have fairly minor adverse safety reactions for the patient; is that correct?
A. That's my understanding.

Q. Is it fair to state that the application, the way that the two products are applied, is comparable?
A. They are both poured onto the hair and left for ten minutes and then washed out.

Q. So, the answer to that question would be yes?
A. Correct.

Q. And Exhibit 41 is the FDA-approved package insert for Sklice; is that accurate?
A. That's what it looks like, yes.

Q. And let's flip to the page Bates labeled SL 2123. It's page seven of the document.
A. Okay.

Q. And that top box, if you will just glance to page six, it's the results of clinical studies which are FDA-approved studies in this case; is that accurate?
A. I assume so.

Q. And looking at this top box on page seven, it states, "Study 1, 76.1 percent effectiveness for Sklice." Do you see that?
A. Yes, I do.

Q. And "Study 2, 71.4 percent effectiveness for the clinical study of Sklice;" correct?
A. That's is correct.

Q. And looking back at the board, Natroba's one-time use clinical study showed 75.9 percent and 68.1 percent; correct?
A. That's what is indicated on the board, yes.

Q. Would you consider that these numbers, 71 to 76 and 68 to 75, are fairly comparable?
A. The numbers are comparable, yes…

Tr. Pollack 853, 855, 846-848, 856-858.

When asked why he thought Sklice had significantly altered or changed the method of treatment Dr. Pollack stated "whether or not it's truly more efficacious or safer, we can argue for weeks about that, but it was incredibly well embraced." Tr. Pollack 883. Thus Dr. Pollack emphasized the success of the product in the market in forming his opinion. However, success is addressed in Section 1.24(b) of the APA in the language that specifies the 40% market share that the product must achieve to constitute a Market Change; it has no bearing on whether the product significantly changed or altered the method for treatment of head lice.

That Sklice met with success could have been the result of superior marketing, attractive pricing,[12] prior knowledge in the medical community of ivermectin, which had been in use since

[12] Sklice had a "very generous" coupon program to keep prices low for the consumer. Exhibit 3 at 24491.

the 1990s,[13] or any number of other factors. In explaining the reasons for Sklice's success Dr. Pollack continued:

> It was a combination of factors. One is obviously marketing. It was a big chunk of it. Two. They can pronounce what this was. They knew what it was... Ivermectin was a household name.

Tr. Pollack 936-937.

The fact that Sklice achieved 40% market share is not determinative of whether Sklice significantly altered or changed the method of treatment of head lice. As Shionogi confirmed, simply achieving 40% is not enough. To demonstrate a Market Change, Shionogi must prove both parts, a 40% market share and change or alteration in the method of treatment of head lice. Tr. Perloff 1752 (Question: "So let me ask you a questions [sic]. Would any product that had achieved 40% satisfy the APA?" Answer: No. "Because there is [sic] two parts. It does have to have those other features. There are two parts."). Indeed, Section 1.24 (b) requires that the product achieve a 40% market share as a "result" of the fact that it significantly altered or change the method of treatment. As Mr. Perloff continued otherwise a product could be discounted heavily in one year and achieve 40% of the market. *Id.*

[13] The FDA label for Sklice dated the U.S. approval for ivermectin, its active ingredient, as 1996. Exhibit 41. It was a long established drug which had been used off label for treating head lice and was now formally introduced as a newly formulated topical medication for treating head lice and commercialized. Articles written in the 1990's noted the use of ivermectin for the treatment of head lice. *See, e.g.*, P. Glaziou 1994 article titled *Efficacy of Ivermectin for the Treatment of Head Lice*, Exhibit 209. The fact that it had an active agent that had long been well known that contributed to its success somewhat contradicts the notion that it "significantly changed or altered the method of treatment."

The Panel FINDS that Sklice did not significantly change or alter the method of treatment of head lice. Accordingly, there was no Market Change within the meaning of Section 1.24(b) of the APA which relieves Shionogi from its obligation to make the minimum payments pursuant to APA § 2.6(b)(v)(2).

F. The Reason for Ulesfia's Failure to Meet Net Sales Targets

Because the Panel has found that no Market Change as defined in Section 1.24(b) of the APA occurred, it does not reach the question of whether or not the failure to achieve the minimum net sales occurred for reasons "other than as a result of a Market Change" as required by APA §2.6(b)(v)(2), if Shionogi is to be excused from payment.

G. Shionogi's Counterclaim

Because the Panel has found that no Market Change occurred, Shionogi's counterclaim for the return of $2,741,163, the sum it paid Summers in 2016 in excess of the percentage owed on actual sales, is denied and its request for a declaratory judgment that a Market Change has occurred is denied.

VII. DAMAGES

Summer seeks an award "that requires Shionogi to pay (1) all unpaid Minimum Payments owed to Summers between 2017 and 2021, totaling $15 million; (2) attorneys' fees; (3) pre-and post-judgment interest; and (4) expenses (*e.g.*,, costs of arbitration and experts)." Claimant's Post-Hrg. Br. at 48-50.

Summers' request for $15 million seeking an acceleration of all payments that would be due through the conclusion of the "Exclusivity Period" on January 1, 2012, is based on a Guaranty and Surety Agreement dated July 16, 2017, executed by Sciele Pharma, Inc. which was delivered

to Summers as part of the purchase transaction effected by the APA (the "Guaranty Agreement").[14] Summers further seeks pre-judgment interest on the entire amount of the Award, commencing on June 12, 2017, the date Shionogi notified Summers of a Market Change.

Summers first sought to recover the value of the accelerated minimum payments for the entire Exclusivity Period in its post-hearing brief. Although both parties briefly addressed this issue in their closing oral arguments the Panel finds that the parties have not had a full opportunity to address the issues raised by this claim, which seeks immediate payment of an additional sum well in excess of $12 million. Accordingly, the Panel defers its resolution of the issues raised by the Guaranty Agreement pending further submissions from the parties.[15]

VIII. ATTORNEYS' FEES AND COSTS

Shionogi maintains that attorneys' fees are precluded by the APA and the costs of the arbitration must be allocated as directed in the APA. Respondent's Post-Hrg. Br. at 49-50. Section 8.5(e) of the APA provides that "Each Party shall bear the expenses of its counsel and

[14] Section 8 of the Guaranty Agreement provides: "If an event of default, breach or unwinding occurs and is continuing under the Purchase Agreement, then all of Guarantor's liabilities of every kind or nature to Guaranteed Party hereunder shall, at Guaranteed Party's option, become immediately due and payable and Guaranteed Party may at any time and from time to time take any and/all actions to enforce all rights and remedies available hereunder or under applicable law to collect Guarantor's liabilities hereunder."

[15] Insofar as recovery under the Guaranty Agreement has been raised in this proceeding, albeit at the end of it, and the Guaranty Agreement provides that any disputes under that Agreement are to be decided in accordance with Section 8.5 of the APA, the arbitration clause, any monetary recovery under the Guaranty is appropriately subject to resolution by arbitration. Shionogi succeeded to the obligations to Summers of the guarantor under the Guaranty Agreement by virtue of its acquisition of that entity, Tr. Zoltan 359,421. Accordingly this proceeding is continued to resolve the issues raised under the Guaranty Agreement.

other experts. The expenses of the arbitration shall be borne by the Parties in proportion as to which each Party prevails or is defeated in arbitration."

However, based on the Guaranty Agreement Summers seeks a recovery of its attorneys' fees and costs and the costs of the arbitration. Claimant's Post-Hrg. Br. at 48-50. Section 2 of the Guaranty Agreement provides: "Guarantor shall also pay or reimburse Guaranteed Party for all reasonable costs and expenses, including without limitation reasonable attorneys' fees, incurred at any time, to enforce, protect, preserve, or defend Guaranteed Parties' rights hereunder.

The Panel defers its determination of attorneys' fees and costs of the arbitration pending further submissions from the parties as to the import of the Guaranty Agreement.

INTERIM AWARD

1. The Panel finds that the territory in which the market and sales requirements of subparagraph (b) of Section 1.24 of the Asset Purchase Agreement dated July 16, 2007 as amended between Shionogi Inc. and Summers Laboratories, Inc. (the 'APA") must be assessed is limited to the United States.

2. The Panel finds that the product "market… for the treatment of head lice" for which the market share must be determined pursuant to Section 1.24(b) of the APA is limited to pharmaceutical products for the treatment of head lice that cannot be bought over the counter.

3. The Panel finds that as of 2016 Sklice had captured over 40% of the Rx market for the treatment of head lice.

4. The Panel finds that Sklice did not "significantly change[] or alter[] the method of treatment of head lice." as specified in section 1.24(b) of the APA.

5. The Panel finds that no Market Change as defined in section 1.24(b) of the APA has occurred up to and including the last date of the hearing in this arbitration, July 27, 2018.

6. Shionogi's counterclaims for monetary damages and for a declaration that a Market Change had occurred is denied.

SPACE INTENTIONALLY INSERTED

7. The issuance of a Final Award will follow further proceedings with respect to the claims asserted and issues raised pursuant to the Guaranty Agreement which will be the subject of further direction from the Panel.

8. This Interim Award may be signed in counterparts, collectively forming one composite signed document.

Dated: October _____, 2018

_____

Harrie Samaras, Co-arbitrator

_____

Hon. Shira A. Scheindlin, Co-arbitrator

_____

Edna Sussman, Chair

State of New York
ss:
County of New York

I, Harrie Samaras do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Interim Award.

_____ _____
Date Harrie Samaras

State of New York
ss:
County of New York

I, Shira A. Scheindlin, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument which is my Interim Award.

_____ _____
Date Shira A. Scheindlin

State of New York
ss:
County of New York

I, Edna Sussman, Esq., do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Interim Award.

_____ _____
Date Edna R. Sussman, Esq.

7. The issuance of a Final Award will follow further proceedings with respect to the claims asserted and issues raised pursuant to the Guaranty Agreement which will be the subject of further direction from the Panel.

8. This Interim Award may be signed in counterparts, collectively forming one composite signed document.

Dated: October 22, 2018

Harrie Samaras, Co-arbitrator

Hon. Shira A. Scheindlin, Co-arbitrator

Edna Sussman, Chair

State of New York

ss:

County of New York

I, Harrie Samaras do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Interim Award.

October 22, 2018
Date

Harrie Samaras
Harrie Samaras

State of New York

ss:

County of New York

I, Shira A. Scheindlin, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument which is my Interim Award.

Oct. 22, 2018
Date

Shira A. Scheindlin
Shira A. Scheindlin

State of New York

ss:

County of New York

I, Edna Sussman, Esq., do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Interim Award.

Oct. 22, 2018
Date

Edna R. Sussman, Esq.
Edna R. Sussman, Esq.

AMERICAN ARBITRATION ASSOCIATION

In the Matter of the Arbitration between:

Summers Laboratories, Inc.,
Claimant / Counter-Respondent

v. **Case No. AAA 01-17-0004-4710**

Shionogi Inc.,
Respondent / Counter-Claimant

SECOND INTERIM AWARD

We, THE UNDERSIGNED ARBITRATORS, having been duly designated in accordance with the arbitration agreement contained in the Asset Purchase Agreement dated July 16, 2007 as amended entered into between Claimant Summers Laboratories, Inc. ("Claimant" or "Summers") and Sciele Pharma Cayman Ltd. which was acquired by Respondent Shionogi Inc. ("Respondent" or "Shionogi") and having been duly sworn, and having duly heard the proofs, allegations, and arguments by said Parties, do hereby issue this SECOND INTERIM AWARD.

I. BACKGROUND

On October 22, 2018, this Panel issued its Interim Award (the "First Interim Award"). Familiarity with the facts set forth in the First Interim Award is assumed and all defined terms used herein are as defined in the First Interim Award.

In brief, the Panel found, *inter alia*, that "Sklice did not 'significantly change[] or alter[] the method of treatment of head lice' as specified in section 1.24(b) of the APA" and that "no Market Change as defined in section 1.24(b) of the APA has occurred up to and including the last date of the hearing in this arbitration, July 27, 2018." Accordingly, Shionogi's obligations with respect to minimum earn out payments (the "Minimum Payments') under the APA were not terminated.

Remaining at issue are Summers' claims based on a Guaranty and Surety Agreement dated July 16, 2007, executed by Sciele Pharma, Inc. which was delivered to Summers as part of the purchase transaction effected by the APA (the "Guaranty") for an accelerated payment of $15 million representing all Minimum Payments that might be due through January 1, 2022, and attorneys' fees and costs of the arbitration. Shionogi maintains that these issues are not properly before this Panel and that, in any case, both claims fail on the merits.

To address these remaining issues the First Interim Award provided:

> The issuance of a Final Award will follow further proceedings with respect to the claims asserted and issues raised pursuant to the Guaranty Agreement which will be the subject of further direction from the Panel.

By email dated October 22, 2018, the Panel directed submissions by the parties, limited strictly to a discussion of issues relating to acceleration of the Minimum Payments under the APA, the award of attorneys' fees and costs, and, if relevant, interest, that were raised by the Guaranty. Claimant was directed to file its submission on November 5, 2018 and Respondent on November 19, 2018.

The Panel further advised that it was holding December 4, 2018, if any party sought oral argument or believed that there were factual issues in dispute relating only to the import of the

Guaranty that required a hearing and requested that the parties advise as to whether the date should be held.

By email dated October 29, 2018 Claimant advised that it did not seek oral argument. By email dated October 30, 2018 Respondent advised that it did not seek oral argument. Neither party sought to avail itself of the Panel's invitation to present further evidence as to the issues raised by the Guaranty.

In accordance with these directions both parties submitted Post-Hearing Briefs and leave was given for Claimant to file a Reply Brief.

II. JURISDICTION

The Guaranty provides that any disputes under that agreement are to be decided in accordance with Section 8.5 of the APA, which provides that "[A]ny dispute, controversy or claim arising out of or *relating to* this Agreement… shall be decided by arbitration in accordance with the rules of the American Arbitration Association (emphasis added)." Thus any claims under the Guaranty are appropriately subject to resolution by the arbitration conducted by this Panel on the underlying dispute held to determine the dispute between the parties as to the terms of and obligations under the APA.

Shionogi does not dispute that the issues raised by the Guaranty are subject to arbitration but contends that the issues cannot be considered in ***this*** arbitration by ***this*** Panel, but rather that a separate arbitration must be commenced. Shionogi Br. at 10. The Panel disagrees and finds that the claims brought under the Guaranty fall squarely within the jurisdiction of this Panel. The language in Section 8.5 of the APA presents a classic "broad" arbitration agreement and accords the Panel jurisdiction as to all matters arising out of or relating to the APA. Disputes arising under

the Guaranty indisputably arise out of or relate to the APA. Shionogi's arguments with respect to *limitations* on the Panel's powers in the exercise of its jurisdiction present a different question and are addressed below.

III. THE GUARANTY

The Guaranty was executed by Sciele Pharma, Inc. and was delivered to Summers as part of Shionogi's purchase transaction effected by the APA. As was found in the First Interim Award, by virtue of its acquisition of the two entities Shionogi succeeded both to the obligations of Sciele Pharma Cayman Ltd. as the principal obligor under the APA, and the obligations of Sciele Pharma, Inc. as the guarantor under the Guaranty. Tr. Zoltan 359, 421. First Interim Award at 1, 37 fn. 15.

The Guaranty was entered into in order "to induce Guaranteed Party [Summers] to sell the Transferred Assets to Sciele Pharma Cayman LTD" as evidenced by the APA. Guaranty Purpose Recital Paragraph.

IV. ACCELERATION OF THE MINIMUM PAYMENTS

Summer seeks "$15 million, the total remaining Minimum Payments due to Summers under the APA." Summers Br. at 1. Summers relies on Section 1 of the Guaranty which provides:

> Guarantor hereby irrevocably and unconditionally guarantees, and becomes surety for, the prompt payment and performance of all debts, liabilities, obligations . . . owing by [Sciele Pharma Cayman, Ltd.] to [Summers] of any kind or nature, present or future, arising under the [APA], now existing or hereafter arising, and any amendments thereto.

Summers further relies on Section 8 of the Guaranty which provides:

> If an event of default, breach or unwinding occurs and is continuing under the Purchase Agreement, then all of Guarantor's liabilities of every kind or nature to Guaranteed Party

> hereunder shall, at Guaranteed Party's option, become immediately due and payable and Guaranteed Party may at any time and from time to time take any and all actions to enforce all rights and remedies available hereunder or under applicable law to collect Guarantor's liabilities hereunder.

Summers contends that these terms of the Guaranty require acceleration and immediate payment by Shionogi of the remaining deferred payments provided under the APA. Summers Br. at 14.

However, as Shionogi correctly argues, "an acceleration clause cannot apply were no liquidated damages amount has been agreed to by the parties, [and] the amounts potentially due in the future are unknown and contingent." Shionogi Br. at 20, citing 22 Am. Jur.2d Damages §545. The APA does not set forth any liquidated damages amount. While the parties agreed to a $3 million annual Minimum Payment, that amount is contingent on the absence of a Market Change, APA § 2.6(b)(v)(2), defined as either a reduction of the incidence of head lice in the Territory, or a significant alteration in the method of treatment of head lice which results in a single Third Party acquiring greater than 40% of the market share for the treatment of head lice. *Id.* § 1.24 (a) & (b). Indeed, Summers' acknowledges that "Shionogi can avoid the $3 million yearly Minimum Payment to Summers" if Shionogi fails to meet the minimum Net Sales as a result of a Market Change, Summers Br. at 5, a fact which as Shionogi states, is "fatal to any claim for acceleration." Shionogi Br. at 21.[1]

[1] Summers cites a string of cases in support of its position that acceleration clauses are enforced by the courts, but none of the cases cited developments that could arise, as are present here, that would cause the requested accelerated payments not to be owing. See, e.g., *Nat'l Audubon Soc., Inc. v. Sonopia Corp.*, No. 09-cv-975, 2010 WL 3911261 (S.D.N.Y. Sept. 1, 2010), *report and recommendation adopted*, No. 09-cv-975, 2010 WL 5373900 (S.D.N.Y. Dec. 22, 2010); *Oscar de la Renta, Ltd. v. Mulberry Thai Silks, Inc.*, No. 08-cv-4341, 2009 WL 1054830 (S.D.N.Y. Apr. 17, 2009); *Kenneth Jay Lane, Inc. v. Heavenly Apparel, Inc.*, No. 03-cv-2132, 2006 WL 728407 (S.D.N.Y. Mar. 21, 2006).

Summers may well be entitled to receive another $12 million in Minimum Payments between now and January 1, 2022, but that entitlement remains contingent on developments in the market for head lice treatments. Under New York law, it is "fundamental that the injured party should not recover more from the breach than [it] would have gained had the contract been fully performed." *Freund v. Washington Square Press, Inc.*, 34 N.Y.2d 379, 382 (1974).

Accordingly, the Panel finds that future potential Minimum Payments that may be due by Shionogi are not "liabilities" now within the meaning of Section 8 of the Guaranty; the contingent nature of these future payments precludes their acceleration.[2]

V. RECOVERY OF ATTORNEYS' FEES AND COSTS

Summers submits that "the clear terms of the Guaranty require Shionogi to reimburse Summers for its attorneys' fees, costs, [and] expenses incurred in protecting against Shionogi's attempt to escape its payment obligations under the APA." Summers Br. at 12. Summers relies on Section 2 of the Guaranty which provides:

> Guarantor shall pay or reimburse Guaranteed Party for all reasonable costs and expenses, including without limitation reasonable attorneys' fees, incurred at any time, to enforce, protect, preserve, or defend Guaranteed Parties rights hereunder.

The Panel finds based on this clear language that Summers is entitled to recover its reasonable arbitration costs and expenses, including attorneys' fees. Following Shionogi's notice, in the summer of 2017, that a Market Change had occurred and that it would no longer be making the Minimum Payments provided in the APA, Summers commenced this arbitration to enforce

[2] In light of the Panel's conclusion that the contingent nature of the obligation precludes acceleration, the Panel does not address Shionogi's contention that it did not have adequate notice of Summers' claim for acceleration pursuant to the Guaranty.

and protect its right to the Minimum Payments. Summers' claim was vigorously opposed in the arbitration. This is precisely the circumstance to which the Guaranty applies and requires reimbursement of expenses, costs and attorneys' fees to Summers by the Guarantor.

Shionogi raises several arguments in opposition to Summers' claim.

First, Shionogi contends that it did not receive adequate notice of claims pursuant to the Guaranty and that accordingly Summers cannot pursue its claim for attorneys' fees under the Guaranty in this arbitration. Shionogi asserts that Summers failed to assert its claims under the Guaranty in its Arbitration Demand, never sought to amend its Demand, and never mentioned the Guaranty at the hearing. Shionogi states that the only references to the Guaranty were in passing at the conclusion of Summers' preliminary hearing brief, briefly in Mr. Procopio's witness statement, raised more substantially in Summers' post-hearing memorandum and became a focus of Summers' closing argument. Shionogi Br. at 8.

In opposition to this contention, Summers points out that Shionogi was on notice from the outset that Summers was seeking attorneys' fees. The AAA demand form in this matter was filed on July 28, 2017 and expressly requested attorneys' fees. Summers' long form Demand dated July 28, 2017 specifically requested as relief "reasonable attorneys' fees, reasonable expenses, and related litigation and arbitration costs." Demand at 9. Exhibit A to Summers' Demand annexed all of the Transaction Documents which included the Guaranty. Summers' pre-hearing memorandum specifically requested reasonable attorneys' fees and costs incurred to defend the arbitration pursuant to the Guaranty. Summers Pre-Hearing Memorandum at 30. Mr. Procopio's witness statement submitted by Summers in advance of the hearing also expressly requested attorneys' fees as set out under the Guaranty.

On these facts, the Panel finds that Shionogi had adequate notice of Summers' claim for attorneys' fees and that such claim was asserted pursuant to the Guaranty. Shionogi's contention that it was prejudiced by the timing and nature of Summers' pleading is not persuasive. Shionogi Br. at 9. Shionogi concedes that it was on notice prior to the hearing of Summers' reliance on the Guaranty, at least for the attorneys' fee claim. Shionogi chose not to ask any questions about the Guaranty at the hearing and chose not to avail itself of the opportunity offered by the Panel, in an effort to eliminate any potential prejudice, to convene an additional hearing for the presentation of evidence on the Guaranty claim.[3] On these facts Shionogi's claim of prejudice is rejected.

Nor does Shionogi's complaint that had it known sooner about the claims under the Guaranty it could have and would have avoided any risk of this liability assist it. Shionogi states that it would have transferred funds to Summers thus eliminating the possibility of any claim under the Guaranty because then the default would not have been "continuing" as required by Section 8 of the Guaranty. Shionogi states it would have simply increased its counterclaim, enabling it to maintain its position. Shionogi Br. at 2, 9. However, the requirement in Section 8 of the Guaranty of a continuing default or breach has no applicability to Section 2 of the Guaranty, which provides an unconditional obligation to reimburse costs, expenses and attorneys' fees.

[3] Contrary to Shionogi's statement, the hearing was not reopened. Shionogi Br. at 8 fn. 1. The hearing was never closed by the Panel, and cannot be "deemed closed," as Shionogi states, on the date of the issuance of the First Interim Award which was issued on October 22, 2018 prior to the October 31, 2018 date to which the parties agreed for the issuance of an "award." Tr. at 1790-1791. As noted above, the First Interim Award provided: "[T]he issuance of a Final Award will follow further proceedings with respect to the claims asserted and issues raised pursuant to the Guaranty Agreement which will be the subject of further direction from the Panel." By email dated October 22, 2018 the Panel directed the submission of additional briefing on that issue. Accordingly, the hearing has not yet been closed. Rather, pursuant to AAA Rule 39 (b) the hearing will be declared closed by the Panel following receipt of additional submissions as directed in this Second Interim Award or as may hereafter be directed.

Shionogi contends that the award of attorneys' fees is precluded by the APA and that the costs of the arbitration must be allocated as directed in the APA**.** Shionogi Br. at 3-7. Shionogi relies principally on Section 8.5(e) of the APA which provides:

> The expenses of the arbitration shall be borne by the Parties in proportion as to which each Party prevails or is defeated in arbitration. Each Party shall bear the expenses of its counsel and other experts.

Shionogi's reliance on this language is misplaced. Section 8.5 (e) specifies the obligations of the "Parties" with respect to attorneys' fees and costs. "Party" and "Parties," to which section 8.5 (e) applies, are expressly defined in the APA as including only Summers, the Seller and Sciele Pharma Cayman Ltd., the Buyer and principal obligor. The obligation undertaken by the guarantor, Sciele Pharma, Inc., was a separate contractual obligation under the Guaranty. Thus Section 8.5(e) of the APA, by its terms, does not apply to the Guarantor.

Moreover, the Guaranty specifically provides that "[A]ll rights and remedies hereunder and under the Purchase Agreement are cumulative and not alternative" thus expressly sanctioning remedies in addition to those that are not provided for or permitted under the APA.

Accordingly, the Panel rejects Shionogi's contention and concludes that Section 8.5 (e) does not limit the Panel's authority to determine whether Summers is entitled to an award of attorneys' fees pursuant to the Guaranty.[4]

[4] Shionogi cites extensive case law in support of its position that Section 8.5 (e) of the APA limits this Panel's authority to award attorneys' fees. Shionogi Br. at 3-6. See, e.g., *Trustees of NY City Dist. CCPF v. Premium Sys., Inc.*, No. 12-cv-1749, 2012 WL 3578849, at *4 (S.D.N.Y. Aug. 20, 2012); *Stewart Tabori & Chang, Inc. v. Stewart*, 723 N.Y.S.2d 492, 494 (1st Dept. 2001). Shionogi's reliance is misplaced. None of the cases cited address an award of attorneys' fees pursuant to an express contractual right which the Panel finds was afforded by the Guaranty.

Shionogi contends that as a matter of law it cannot guarantee its own performance and accordingly the Guaranty was rendered a nullity when Shionogi acquired all rights and obligations under both the APA, as the principal contract, as well as under the Guaranty. Shionogi Br. at 11-12.

The cases cited by Shionogi in support of its position are inapposite.[5] None of those cases address a corporate restructuring or acquisition, pursuant to which the guarantor, for the first time, and at a point in time subsequent to the transaction, becomes one and the same as the principal obligor. Nor do any of the cases address a situation, such as we have here, where the Guaranty provides for remedies additional to those available under the principal agreement. Accepting Shionogi's contention would lead to an unreasonable outcome depriving Summers of the benefits of the Guaranty, which was an integral part of the transaction and offered to "induce" Summers to enter into the transaction and transfer its assets. The law does not sanction such evasion of responsibility through corporate acts. *See, e.g., Leslie Fay, Inc. v. Rich*, 478 F. Supp. 1109, 1117 (S.D.N.Y. 1979) ("Defendants should not be allowed to evade their personal obligations by virtue of corporate acts that were fully within their control . . .").

[5] *See, Playboy Enters., Inc. v. Sanchez-Campuzano*, No. 01-cv-226, 2011 WL 13124279 (S.D. Tex. Jul. 12, 2011) (denying Rule 60 (b) motion finding there was no evidence that the guarantor was guaranteeing its own obligations at the time of the initial transaction); *Int'l Paper Co. v. April Agro Indus.*, 747 F. Supp. 111, 115 (D.P.R. 1990) (holding that the document in issue was insufficient to constitute an express guarantee); *BAII Banking Corp. v. UPG, Inc.*, No. 86-cv-5544, 1990 WL 160889 (S.D.N.Y. Oct. 17, 1990) (granting an unopposed summary judgment application where the complaint alleged that the party had guaranteed its own performance); *Anti-Hydro Co., Inc. v. Castiglia*, 461 N.Y.S.2d 87, 88 (4th Dept. 1983) (holding that the personal guarantee issued to support purchases by sole proprietorship was not enforceable with respect to transactions entered into subsequently with a different corporate entity).

Shionogi also raises Section 8.2 of the APA, which provides that "in the event of any conflict between the provisions of this Agreement and the provisions of … any … Ancillary Agreement, the provisions of this Agreement shall prevail. Shionogi Br. at 13. However, as Shionogi concedes, the Guaranty is not one of the Ancillary Agreements as defined in the APA making this provision irrelevant to the Panel's analysis.

Shionogi suggests that the amendment of the APA supplanted any obligations under the Guaranty. Shionogi Br. at 13 – 14. However, Section 1 of the Guaranty defeats this argument in expressly providing that:

> [G]uarantor hereby irrevocably and unconditionally guarantees … all debts, liabilities, obligations … owing by the Buyer to the Guaranteed Party of any kind or nature, present or future, arising under the Purchase Agreement … and any amendments thereto (all the foregoing collectively, "Obligations").

Moreover, the First Amendment to the APA, by its terms, does not void, extinguish or override the Guaranty. To the contrary, the First Amendment makes clear that all obligations of Shionogi under the Agreement remain, and, "except as amended hereby all of the terms and conditions of the Agreement shall continue in full force and effect." Hearing Exhibit 2.[6]

Finally Shionogi turns to a construction of the pertinent language of the Guaranty and asserts that if the Panel were to finds that the Guaranty survives, it is ambiguous and should be construed to find that the attorneys' fees sought by Summers are not available.

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[6] *Lnzro Pizza Empire, Inc. v. Brown*, 645 N.Y.S.2d 379 (4th Dep't 1996), cited by Shionogi, stands only for the proposition that "where the parties have clearly expressed or manifested their intention that a subsequent agreement supersede or substitute for an old agreement, the subsequent agreement extinguishes the old one and the remedy for any breach thereof is to sue on the superseding agreement." There is no such superseding agreement here. On the contrary, the amendment to the APA reaffirms all obligations except as explicitly amended.

Shionogi contends that the attorneys' fee provision applies only to attorneys' fees incurred in connection with enforcement of the Guaranty itself because it references the Guarantor's obligation to pay attorneys' fees incurred to enforce or defend Summers' "*rights hereunder*." Shionogi Br. at 14–16 (emphasis added). However, the definition of "Obligations" in the Guaranty, as quoted above, establishes that Summers' rights under the Guaranty extend to *all* obligations owing to Summers under the APA. Thus, the reference in Section 2 to Summers' "rights hereunder" cannot be read to cover only those attorneys' fees incurred in enforcing the Guaranty. The Guaranty's express provision in Section 5 that "[A]ll rights and remedies hereunder and under the Purchase Agreement are cumulative and not alternative" reinforces this conclusion and also defeats Shionogi's second contention that there is a conflict between Section 8.5 of the APA and Section 2 of the Guaranty. The remedies are cumulative and, as discussed above, there is no conflict between Section 8.5 (e) of the APA and the Guaranty because different parties made the commitment. That such a provision was agreed to by the parties is logical given that most of the payments under the APA were to be made over the course of many years and absent this disincentive, Shionogi could repeatedly fail to pay and repeatedly require Summers to commence arbitration proceedings to enforce its rights.

The Panel finds that Section 2 of the Guaranty is not ambiguous and finds that Summers is entitled to be "reimbursed for all reasonable costs and expenses, including, without limitation, reasonable attorneys' fees, incurred to enforce, protect, preserve or defend its rights."

VI. INTEREST AND COSTS

Having concluded that the Guaranty does not entitle Summers to an acceleration of the Minimum Payments under the APA, the Panel turns to the question of interest, which was left

unresolved in the First Interim Award pending decision on the issues raised under the Guaranty. Summers urges the Panel to adopt the 9% prejudgment New York interest rate commencing on June 12, 2017, the date Shionogi notified Summers of a Market Change.

Shionogi directs the Panel's attention to Section 2.6 (c) of the APA which provides that late payments under the Agreement, "will bear simple interest at the lower of (a) the US prime rate plus two (2) basis points as reported in the Wall Street Journal, Eastern Edition on the due date … or (b) the maximum rate permitted under applicable law." Shionogi maintains that the proper date for the commencement of the interest calculation is when the $3 million Minimum Payment for 2017 came due on January 30, 2018. Parties Joint Submission on Interest submitted September 15, 2018.

The Panel finds that the proper date for the commencement of the interest calculation is when payments were due under the APA. Accordingly, pursuant to Section 2.6(b)(v)(1) of the APA interest is to commence on the quarterly payments due on Net Sales of Ulesfia in 2017 and 2018 thirty (30) days after the end of each Calendar Quarter. Interest on the true up required pursuant to Section 2.6(b)(v)(2) of the APA for the $3 million Minimum Payment for 2017 is to commence on January 30, 2018.

The Panel's findings as to whether or not there had been a Market Change and consequently whether or not Shionogi's obligation to make the Minimum Payments were terminated were made in the First Interim Award pursuant to the APA and not the Guaranty. Accordingly, the Panel finds that the interest rate specified in the APA is applicable rather than the 9% statutory rate urged by Summers as the interest rate pursuant to the Guaranty. The Panel further finds that because the interest rate for late payments was specified in the APA, it should be applied, and overrides the statutory 9%. *See Heimbinder v. Berkovitz*, 693 N.Y.S.2d 200, 2002 (2d Dept. 1999) ("when the

contract provides that interest shall be paid at a specified rate until the principal shall be paid, the contract rate governs").

The Panel notes that on November 16, 2018, Shionogi tendered payment of $3,239,460 to Summers, representing "the total of (a) the $3 million Minimum Payment for Calendar Year 2017 pursuant to Section 2.6(b)(v)(2) of the APA; (b) $142,250 in late payment interest on (a) through November 16, 2018 pursuant to Section 2.6 (c) of the APA; (c) $95,504 representing quarterly earn out payments based on actual net sales of Ulesfia for Q1 – 3 2018, pursuant to section 2.6(b)(v)(1) of the APA; and (d) $1,076 in late payment interest on (c) through November 16, 2018, pursuant to Section 2.6(c) of the APA." Shionogi Br. Exhibit 1, Email from Shionogi to Summers dated November 16, 2018.

Shionogi recognizes that pursuant to the Section 8.5 (e) of the APA "the expenses of the arbitration shall be borne by the parties in proportion as to which each party prevails or is defeated in arbitration." Shionogi urges that pursuant to this Section the cost of the arbitration should be apportioned 70/30 with Shionogi bearing the greater burden on the grounds that Shionogi prevailed on some of the factual determinations made in the First Interim Award. Shionogi Br. at 28 – 29. The Panel need not address how, if any, an allocation would have been made pursuant to the terms of the APA. The Guaranty controls this issue as well and provides that "Guarantor shall reimburse Summers for "all reasonable costs and expenses, including … reasonable attorneys' fees." For the reasons discussed above, the Panel finds Section 2 of the Guaranty governs with respect to this issue and Summers is entitled to recover all of its reasonable costs and expenses incurred in this arbitration, together with its reasonable attorneys' fees.

SPACE INTENTIONALLY INSERTED

SECOND INTERIM AWARD

1. Acceleration of the future Minimum Payments specified in the APA is denied; they are contingent on developments in the market and cannot be accelerated pursuant to the Guaranty.
2. Summers is entitled to reimbursement by Shionogi pursuant to the Guaranty for all reasonable costs and expenses, including, without limitation, reasonable attorneys' fees, incurred at any time, to enforce, protect, preserve, or defend its rights commencing with the date of the filing of the Demand, July 28, 2017.
3. Interest on amounts not paid on the dates due pursuant to the APA by Shionogi shall be calculated at the Prime plus 2 basis point rate specified in the APA.
4. Interest shall run on the quarterly Net Sales of Ulesfia in 2017 and 2018 thirty (30) days after the end of each Calendar Quarter.
5. Interest shall commence to run on the difference between the total of the quarterly Net Sales of Ulesfia in 2017 and the $3 million Minimum Payment due for 2017 on January 30, 2018.
6. Counsel shall confer and advise by January 8, 2019 as to the amount, if any, still owing by Shionogi to Summers pursuant to the APA for quarterly, Minimum Payments or interest due under the APA following the payment made by Shionogi to Summers on November 16, 2018, calculated in accordance with the decisions of this Panel as of the date of this ruling.
7. On January 8, 2019, Summers shall submit its application in support of its claim for attorneys' fees, expenses and costs which shall include the date, timekeeper, time spent, hourly rate, a description of the tasks performed, as well as a summary list of

timekeepers and total fees for each timekeeper and an itemized list of out-of-pocket expenses.

8. Shionogi may submit a response to Summers' application for attorneys' fees, expenses and costs on January 18, 2019. Summers may request leave to file a response if an objection is lodged by Shionogi.

9. The Panel reserves jurisdiction to determine whether there are any additional sums owing by Shionogi to Summers under the APA, the award of reasonable attorneys' fees, expenses and costs to Summers and for the calculation and allocation of the administrative fees and expenses of the AAA and the compensation of the arbitrators.

10. This Second Interim Award may be executed in counterparts, each of which shall be deemed an original, and all of which shall constitute one and the same instrument.

Dated: December 26, 2018

_____

Harrie Samaras, Co-arbitrator

_____

Hon. Shira A. Scheindlin, Co-arbitrator

_____

Edna Sussman, Chair

State of Pennsylvania
ss:
County of Chester

I, Harrie Samaras do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Second Interim Award.

December 26, 2018
_____ _____
Date Harrie Samaras

State of New York
ss:
County of New York

I, Shira A. Scheindlin, do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument which is my Second Interim Award.

December 26, 2018
_____ _____
Date Shira A. Scheindlin

State of New York
ss:
County of Westchester

I, Edna Sussman, Esq., do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Second Interim Award.

December 26, 2018
_____ _____
Date Edna Sussman

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Harrie Samaras, Co-arbitrator

Hon. Shira A. Scheindlin, Co-arbitrator

Edna Sussman, Chair

State of Pennsylvania

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County of Chester

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State of New York

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December 26, 2018

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Shira A. Scheindlin

State of New York

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County of Westchester

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December 26, 2018

Date

Edna Sussman

AMERICAN ARBITRATION ASSOCIATION

In the Matter of the Arbitration between:

Summers Laboratories, Inc.,
Claimant / Counter-Respondent

v. **Case No. AAA 01-17-0004-4710**

Shionogi Inc.,
Respondent / Counter-Claimant

FINAL AWARD

We, THE UNDERSIGNED ARBITRATORS, having been duly designated in accordance with the arbitration agreement contained in the Asset Purchase Agreement dated July 16, 2007 as amended entered into between Claimant Summers Laboratories, Inc. ("Claimant" or "Summers") and Sciele Pharma Cayman Ltd. which was acquired by Respondent Shionogi Inc. ("Respondent" or "Shionogi") and having been duly sworn, and having duly heard the proofs, allegations, and arguments by said Parties, do hereby issue this FINAL AWARD.

I. BACKGROUND

On October 22, 2018, this Panel issued its Interim Award (the "First Interim Award"). Familiarity with the facts set forth in the First Interim Award is assumed and all defined terms used herein are as defined in the First Interim Award.

In brief, the Panel found, *inter alia,* that "Sklice did not 'significantly change[] or alter[] the method of treatment of head lice' as specified in section 1.24(b) of the APA" and that "no

Market Change as defined in section 1.24(b) of the APA has occurred up to and including the last date of the hearing in this arbitration, July 27, 2018." Accordingly, Shionogi's obligations with respect to minimum earn out payments (the "Minimum Payments') under the APA were not terminated.

The First Interim Award is annexed hereto and incorporated herein by reference.

On December 26, 2018, this Panel issued its Second Interim Award (the "Second Interim Award"). In brief, the Panel found, *inter alia*, that pursuant to the Guaranty and Surety Agreement dated July 16, 2007, executed by Sciele Pharma, Inc. which was delivered to Summers as part of the purchase transaction effected by the APA (the "Guaranty"), Summers was not entitled to acceleration of the future Minimum Payment specified in the APA but was entitled to reimbursement by Shionogi pursuant to the Guaranty for all reasonable costs and expenses, including, without limitation, reasonable attorneys' fees incurred in enforcing Shionogi's obligations under the APA.

The Second Interim Award is annexed hereto and incorporated herein by reference.

Remaining to be addressed is the determination of reasonable costs and reasonable attorneys' fees.

II. COSTS

Summers seeks $232,828.21 for AAA expenses, $300,000 for the expense for one expert, $40,570 for a second expert and $116,705.69 for various expenses including, *inter alia*, delivery services, transcripts, photocopying, Westlaw charges, duplicating, hotel and out-of-town travel, document binding, supplies, and the court reporter for a total of $690,103.90.

Shionogi objects to the $300,000 charge for one of the experts. That sum represents a 33% reduction by the expert of his fees. The Panel finds that the expert presented evidence that was fundamentally flawed and based on faulty data and when confronted at the hearing with accurate facts attempted to defend his position by misleadingly stating false facts to the Panel. On these facts the Panel finds that Summers is not entitled to be reimbursed for the cost of that expert, both because of his conduct at the hearing and because his evidence necessitated additional and unnecessary costs in preparation and examination at the hearing and subsequent to the hearing by all parties and the Panel.

The Panel finds that Summers is entitled to the sum of $390,103.90 for its costs.

III ATTORNEYS' FEES

Summers seeks $2,213,178 in attorneys' fees.

In support of its fee application Summers submitted the declaration of its counsel, John D. Huh, and provided a spreadsheet itemizing the name of the time keeper, the time keeper's title, the work date, the time card description, the hours billed and the dollars billed with the billable rate for the individuals for whom billable time was incurred. Summers also submitted the expert report of attorney David W. Ichel as to the reasonableness of the attorneys' fees and expenses.

Shionogi objects to the amount of attorneys' fees sought on various grounds.

A. Fees incurred to recover attorneys' fees

We turn first to Shionogi's objection to recovery of fees incurred in connection with Summers' effort to recover its attorneys' fees, totaling approximately $280,000, including both its

initial fee application submission dated January 8, 2019 and its supplementary fee application submission dated February 12, 2019.

The parties have presented numerous cases in support of their respective positions. Some of those cases, for example, relate to recoveries of attorneys' fees pursuant to statutory rights and others pursuant to contractual commitments. The Panel finds pertinent to its analysis only those cases which, like the one before us, relate to contractual commitments for payment of attorneys' fees.

The Second Circuit set forth the rule as to the recovery of attorneys' fees incurred in connection with an application to recover fees in cases arising from a contractual agreement to pay attorneys' fees. "[A] general contract provision for the shifting of attorneys' fees does not authorize an award of fees for time spent in seeking the fees themselves." *F.H. Krear v. Nineteen Named Trustees*, 810 F. 2d 1250, 1266 (2d Cir. 1987).

This principle was confirmed more recently in *Kerr v. John Thomas Financial*, No. 14-cv-9168, 2017 WL 1609224 (S.D.N.Y. May 1, 2017) in which the court noted that the party had correctly stated that "the general contract provision for the shifting of attorneys' fees does not authorize an award of fees for time spent in seeking the fees themselves." *Id.* at *2. However, the court continued that "the parties may contract for such an allowance." *Id.* In *Kerr* the agreement provided for recovery of attorneys' fees incurred during "any judicial or arbitral proceeding to construe or enforce any provision of this agreement." The court found that "to construe or enforce any provision of this agreement" included the fee recovery provision which was itself part of the agreement. *Id.*

We turn to the language of the Guaranty. The Guaranty provides:

> Guarantor shall pay or reimburse Guaranteed Party for all reasonable costs and expenses, including without limitation reasonable attorneys' fees, incurred at any time, to enforce, protect, preserve, or defend Guaranteed Parties rights hereunder.

Unlike the contract in *Krear* which provided only that the "prevailing party" would "have the right to reimbursement of reasonable attorney's fees," *Krear* at 1261, the language of the Guaranty at issue provides for recovery of "*all* reasonable costs and expenses, including *without limitation* reasonable attorneys' fees, *incurred at any time* to enforce . . . Guaranteed Parties rights hereunder (emphasis added)." The Panel finds that language similar to the coverage in *Kerr* for attorneys' fees incurred to enforce "any provision of this agreement" and thus, as in *Kerr*, the "rights" under the Agreement include recovery of attorneys' fees for time spent recovering those fees. Indeed, in the Second Interim Award the Panel stated "the reference in Section 2 to Summers' 'rights hereunder' cannot be read to cover only those attorneys' fees incurred in enforcing the Guaranty," Second Interim Award at 12, thus, in essence, already finding that there was an entitlement to attorneys' fees incurred in enforcing the Guaranty's right to such fees.

Accordingly, the Panel finds that Summers is entitled to the $280,000 in attorneys' fees incurred in order to recover its attorneys' fees subject to any reduction based on the Panel's views of the reasonableness of this amount of fees.

B. The reasonableness of the attorneys' fees

Summers correctly states that the standard to be applied by the Panel in reviewing its application is whether or not the fees requested are "reasonable." As the Second Circuit stated

in *Diamond D Enters. USA Inc. v. Steinsvaag*, 979 F.2d 14, 19 (2d Cir. 1992) with respect to a contractual entitlement to attorneys' fees:

> When a contract provides that in the event of litigation the losing party will pay the attorneys' fees of the prevailing party, the court will order the losing party to pay whatever amounts have been expended . . . so long as those amounts are not unreasonable.

Recent cases based on a contractual right to attorneys' fees have similarly examined whether the fees sought are reasonable. *See, e.g., Star Funding, Inc. v. Vault Minerals, LLC*, No. 15-cv-3026, 2017 WL 7791558, at *7 (S.D.N.Y. Aug. 10, 2017) ("When the contract provides for an award of attorneys' fees, the [court] is to decide… whether a party may recover such fees; if the [court] decides that a party may recover attorneys' fees, then the judge is to determine a reasonable amount of fees." (citation omitted); *Tackney v. WB Imico Lexington Fee, LLC*, No. 10-cv-2734, 2015 WL 1190096, at *3 (S.D.N.Y. Mar. 16, 2015) (where the losing party is contractually bound to pay the attorneys' fees of the prevailing party, the court will order payment "so long as those amounts are not unreasonable.") The *Tackney* court noted that an award of attorneys' fees is "within the discretion of the court" and the courts have "broad discretion." *Id.*

Summers suggests that the fact that its client paid the fees "creates a presumption that the fees are reasonable." Summers Reply at 2. But Summers' Fee Application, to which it refers back for support for this proposition, more accurately states the courts' position as quoted above that the "court will order the [responsible] party to pay whatever amounts have been expended… *so long as those amounts are not unreasonable*" (emphasis added). Summers' Application for Attorneys' Fees

at 4-5, quoting *Diamond D Enters, supra.* Thus, the requirement that reasonableness be assessed is expressly recognized.

The requirement that an examination be conducted as to whether the attorneys' fees request is reasonable is based on sound policy. As the court stated in the *Diamond D Enters* case cited by Summers, "[b]ecause a fee-shifting clause can produce perverse incentives for a litigant (and his attorneys) … courts must scrutinize fee requests to ascertain whether they are reasonable." (citations omitted).

In approaching an analysis of reasonableness, while the standard lodestar approach may not be required as such, see *Peter Fabrics, Inc. v. S.S. "Hermes,"* 765 F.2d 306, 317-19 (2d Cir. 1985), in fact the courts approach the analysis in a similar fashion and look first to the hourly rates charged by the lawyers, including, *inter alia,* their qualifications and the customary fees charged, and then to the number of hours billed and whether they were reasonably expended. *See Star Funding, Inc, supra; Tackney, supra.*

Shionogi does not object to the hourly rates charged and the Panel finds them to be reasonable. Summers' counsel were highly qualified and skilled and their hourly rates are well within a reasonable range. *See* Expert Report of David W. Ichel at ¶¶ 39 – 56.

Shionogi however objects to the fee request on several other grounds and itemizes in its brief the line items in Summers' time record entries as to which it lodges its objections. Shionogi's objections include:

i. Time spent in connection with the expert whose fees have been disallowed.

ii. Travel time billed at 100% of time, citing *Siegel v. Bloomberg L.P.*, No. 13-cv-1351, 2016 WL 1211849, at *7 (S.D.N.Y. Mar. 22, 2016) ("a 50 percent discount for travel time is the customary practice in this District.") (collecting cases).

iii. Excessive, duplicative and unnecessary work, citing *Kerr v. John Thomas Fin.*, No. 14-cv-9168, 2017 WL 435826, at *8 (S.D.N.Y. Jan. 31, 2017), report and recommendation adopted as modified, No. 14-cv-9168, 2017 WL 1609224 (S.D.N.Y. May 1, 2017).

iv. Vague entries insufficient to support the request, citing *Dixon v. Agbai*, No. 15-cv-850, 2016 WL 3702749, at *17 (S.D.N.Y. July 8, 2016), report and recommendation adopted, No. 15-cv-850, 2016 WL 5660246 (S.D.N.Y. Sept. 28, 2016).

Shionogi urges that the fees be reduced by 40% to arrive at a reasonable amount for attorneys' fees, citing *Praesidian Capital Opportunity Fund III v. Persinger*,. No. 17-cv-8376, 2018 WL 1578365, at *4 (S.D.N.Y. Mar. 28, 2018) (applying across-the-board reduction of 40% when court found attorney's time expenditures excessive where plaintiff's counsel spent significant time after the complaint was filed despite the fact that defendant never made an appearance); *MB Fin. Bank, N.A. v. 56 Walker, LLC.*, No. 11-cv-5538, 2011 WL 6338808, at *4 (S.D.N.Y. Dec. 19, 2011) (applying across-the-board reduction of 40% to the plaintiff's attorneys' hours in a fee application pursuant to the federal removal statute finding that the hours were excessive and expended to pursue a removal which was plainly improper).

The Panel has reviewed Summers' entries and considered both parties' arguments as to the reasonableness of the hours expended. The Panel finds that Shionoigi's 40% reduction is not justified by the facts but finds that Summers' attorneys' fee application should be reduced by 25% in order to arrive at a reasonable fee figure. The Panel concludes that this reduction in fees is

appropriate based on our review of the time records submitted by Summers which reveal time spent both before and after the final hearing related to discredited expert testimony, multiple attorney attendance at depositions, excessive billing of travel time, and generally duplicative tasks performed by multiple attorneys. The Panel need not "set forth item by item findings… Rather, in dealing with items that are excessive, redundant or otherwise unnecessary, the court has discretion simply to deduct a reasonable percentage of the number of hours claimed as a practical means of trimming the fat from the fee application." *Star Funding supra*, at *7 (citations omitted).

The Panel finds that Summers is awarded $1,659,883 in attorneys' fees after applying the 25% reduction to the attorneys' fees sought. (75% of $2,213,178 equals $1,659,883).

III. INTEREST

Pursuant to the Second Interim Award, the Panel directed the parties to "advise by January 8, 2019 as to the amount, if any, still owing by Shionogi to Summers pursuant to the APA for quarterly Minimum Payments or interest due under the APA following the payment made by Shionogi to Summers on November 16, 2018, calculated in accordance with the decisions of this Panel."

The Panel was not advised that any such sums remained owing.

Accordingly, the Panel finds that Shionogi has made the payments to Summers required pursuant to the First Interim Award and the Second Interim Award.

AWARD

1. The Panel finds that the territory in which the market and sales requirements of subparagraph (b) of Section 1.24 of the Asset Purchase Agreement dated July 16, 2007 as amended between Shionogi Inc. and Summers Laboratories, Inc. (the 'APA") must be assessed is limited to the United States.

2. The Panel finds that the product "market… for the treatment of head lice" for which the market share must be determined pursuant to Section 1.24(b) of the APA is limited to pharmaceutical products for the treatment of head lice that cannot be bought over the counter.

3. The Panel finds that as of 2016 Sklice had captured over 40% of the Rx market for the treatment of head lice.

4. The Panel finds that Sklice did not "significantly change[] or alter[] the method of treatment of head lice" as specified in section 1.24(b) of the APA.

5. The Panel finds that no Market Change as defined in section 1.24(b) of the APA has occurred up to and including the last date of the hearing in this arbitration, July 27, 2018.

6. Shionogi's counterclaims for monetary damages and for a declaration that a Market Change had occurred are denied.

7. Shionogi shall pay the sum of US$ $1,659,883 (One Million Six Hundred and Fifty Nine Thousand Eight Hundred and Eighty Three Dollars) in payment of Summers' attorneys' fees and US$390,103.90 (Three Hundred and Ninety Thousand One Hundred and Three Dollars and Ninety Cents) in payment of Summers' costs.

8. The Administrative fees and expenses of the AAA totaling $52,700.00 are to be borne by Shionogi, Inc.. The Compensation and expenses of Arbitrators totaling $388,581.40 are to be borne by Shionogi, Inc.. Therefore, Shionogi, Inc. has to pay Summers Laboratories, Inc., an amount of $226,790.73.
9. This Final Award renders a final decision on the merits of all claims submitted to this Arbitration. All claims not expressly granted herein are hereby denied.

Dated: 3.1, 2019

_____

Harrie Samaras, Co-arbitrator

_____

Hon. Shira A. Scheindlin, Co-arbitrator

_____

Edna Sussman, Chair

State of Pennsylvania
ss:
County of Chester

I, Harrie Samaras do hereby affirm upon my oath as Arbitrator that I am the individual described in and who executed this instrument, which is my Final Award.

3.1.2019
Date

_____
Harrie Samaras

State of New York
ss:
County of New York

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_____
Date

_____
Shira A. Scheindlin

State of New York
ss:
County of Westchester

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Date

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Edna Sussman

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9. This Final Award renders a final decision on the merits of all claims submitted to this Arbitration. All claims not expressly granted herein are hereby denied.

Dated: March 1, 2019

_____

Harrie Samaras, Co-arbitrator

_____

Hon. Shira A. Scheindlin, Co-arbitrator

Edna Sussman, Chair

State of Pennsylvania

ss:

County of Chester

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Date Harrie Samaras

State of New York

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County of New York

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State of New York

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County of Westchester

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March 1, 2019 _____

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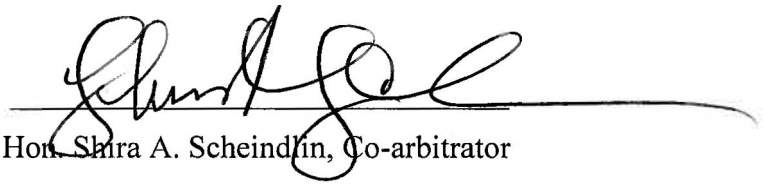

Hon. Shira A. Scheindlin, Co-arbitrator

Edna Sussman, Chair

State of Pennsylvania

ss:

County of Chester

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Date Harrie Samaras

State of New York

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3/1/19 _____

Date Shira A. Scheindlin

State of New York

ss:

County of Westchester

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Date Edna Sussman